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The *Lundbeck* case and the concept of potential competition

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Sandra Marco Colino
Assistant Professor, Chinese University of Hong Kong.
Director, Centre for Financial Regulation and Economic Development (CFRED)

Niamh Dunne
Assistant Professor, London School of Economics and Political Science

Knut Fournier
PhD Candidate, Leiden University,
Chairperson, Hong Kong Competition Association

Sofia Oliveira Pais
Professor of Law, Faculdade de Direito-Porto, Universidade Católica Portuguesa, and Jean Monnet Chair

Derek Ritzmann
Senior Vice President, Compass Lexecon, Hong Kong

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ABSTRACT

Antitrust rules have been brought into play in situations whereby a company tries to prevent, or at least delay, the entry into the market of potential competitors. This issue has gained prominence in the context of patents and intellectual property (IP) rights in the pharmaceutical industry. Patent holders of a drug sometimes enter into a 'reverse payment agreement' with generics manufacturers, in order to settle prospective patent litigation. The sum agreed might also cover delaying the entry of the generic version of the drug into the market ('pay-for-delay' settlement), which could be harmful for competition. And yet the fact remains that, when reverse payment agreements are entered into, the generics manufacturers are not actual competitors of the patent holder. To what extent should the application of competition extend to a future threat which may never materialise? This paper brings together a panel of experts in order to analyse these issues, recently highlighted by the General Court's judgment in the Lundbeck case.

Le droit de la concurrence a trouvé à s'appliquer lorsqu'une entreprise tente d'empêcher, ou du moins de retarder, l'entrée d'un concurrent potentiel sur le marché. L'importance de cette problématique s'est développé dans le contexte des brevets et droits de propriété intellectuelle (PI) dans l'industrie pharmaceutique. Les titulaires de brevets concluent parfois des «accords de paiements inversés» avec les fabricants de génériques pour prévenir le risque de litiges relatifs aux brevets. Ces paiements sont parfois effectués dans le but de retarder l'entrée du médicament générique sur le marché («pay-for-delay»), ce qui peut s'avérer néfaste pour la concurrence. Au demeurant, les fabricants de génériques ne sont pas des concurrents réels du titulaire de brevets au moment où ces accords de paiements inversés sont conclus. Dans quelle mesure le droit de la concurrence devrait-il servir à prévenir une menace future qui ne se matérialisera peut-être jamais ? Plusieurs spécialistes se sont interrogés sur ce débat qui a récemment été au cœur de l'affaire Lundbeck devant le Tribunal de première instance de l'Union européenne.

General introduction

Sandra Marco Colino
s.marcocolino@cuhk.edu.hk
Assistant Professor, Chinese University of Hong Kong.
Director, Centre for Financial Regulation and Economic Development (CFRED)

1. Should competition law be applied to the future? As far-fetched as the question might initially seem, antitrust rules have been brought into play in situations whereby a company tries to prevent, or at least delay, the entry into the market of future—potential—competitors. This issue has become strikingly prominent in the context of patents and intellectual property (IP) rights in the pharmaceutical industry. The controversy can be summed up as follows: when a company develops a new drug, it will normally resort to patents to protect its investment in innovation and prevent other manufacturers, who could potentially make a similar generic product, from entering the market. But any patent awarded to the drug originator is finite in time, and will come with an expiry date; moreover, even during its lifespan the patent does not always grant full immunity from competition in practice. Generic producers may decide to test the boundaries of the protection afforded by the patent by either entering the market anyway—in which case the patent holder would be forced to resort to costly litigation to

defend its IP rights—or by challenging the validity of the patent in court.[1] And while a small number of patents is taken to court, half of those which are end up being declared invalid. To avoid this uncertainty, the originator company may wish to enter into a "reverse payment agreement," which involves paying the generic producers to settle prospective patent litigation (hence also referred to as "reverse payment settlement").[2] The term "reverse" refers to the unusual fact that it is the plaintiff (originator) who pays the defendants (generic manufacturers).[3] The sum agreed might also cover delaying the entry of the generic version of the drug into the market ("pay-for-delay" settlement), thereby unorthodoxly prolonging the protection of patent after its inevitable expiration.

2. Schemes of this nature are bound to set off alarm bells in the mind of the antitrust erudite. Delaying the entry of would-be competitors would almost certainly entail pushing back the benefits typically derived from a competitive market, the very ones that competition law was designed to protect. And yet the fact remains that, when reverse payment agreements are entered into, the generic manufacturers are not actual competitors of the patent holder. Unless they infringe the IP rights of the originator, the generic version of the drug will only hit the market once the basic patent is no longer in force. To what extent, therefore, should the application of competition extend to a future threat which may never materialise?

3. To be clear, the risks for competition inherent to pay-for-delay agreements are undoubtedly substantial. The availability of the generic drug would be expected to benefit consumers by increasing choice and bringing prices down. Beyond reverse payment settlements, drug manufacturers have been known to inflate prices when they do not face competition and/or their prices are not regulated. For instance, in 2016 the companies Pfizer and Flynn Pharma were fined £90 million by the UK's Competition and Markets Authority (CMA) for charging excessive prices, following a colossal 1,600% increase in the cost of phenytoin sodium capsules the moment the price ceased to be subject to regulation.[4] To make matters worse, this may well come out of the taxpayers' pockets, since medicines are frequently covered by national health-care systems. This makes the potential negative consequences of anticompetitive behaviour in this sector particularly far-reaching and worrying. In this context, it is not surprising that antitrust authorities pay special attention to the actions of pharmaceutical companies, and that reverse payments are looked upon with suspicion.

4. In recent years, various antitrust enforcers have specifically considered the drug makers' pay-for-delay practices. Their verdicts are generally unfavourable, but in different degrees. Therefore, the extent to which such arrangements are unlawful very much depends on the specific jurisdiction in which the agreements are investigated. In the US, the leading case is *Actavis*.[5] The Federal Trade Commission originally tried to apply a presumption of illegality to reverse payment agreements. The Supreme Court, while ruling that said arrangements could indeed be challenged under antitrust law, established that they should be subject to the rule of reason analysis. Notably, the recent ruling of the EU General Court (GC) in *Lundbeck* suggests that a harsher treatment will be applied under EU competition law. It confirms that these agreements are to be considered restrictions of competition by object under Article 101(1) TFEU.[6] This position had been defended by the European Commission in its own decision against the pharmaceutical company, which the GC ratified in its judgment.[7] A similar stance was also adopted in the UK by the CMA when it imposed a £45 million fine on GlaxoSmithKline for paying £50 million to generic producers of the drug paroxetine to delay their entry into the UK market,[8] in breach of the Chapter I Prohibition and Article 101(1) TFEU. In the ongoing (as of 1 March 2017) appeal before the Competition Appeals Tribunal (CAT), the CMA stated that such practices are "*by nature antithetical to the competitive process*."[9] Moreover, on 3 March 2017, the CMA issued a new statement of objections against drug makers Concordia and Actavis for entering into an agreement to discourage the former from making a competing version of the latter's hydrocortisone tablets. Actavis has also been accused of abusing its dominant position by delaying Concordia's entry into the market.[10]

5. Clearly, there is no question that these agreements are an important concern for antitrust authorities. What makes the above decisions particularly interesting is that they rely almost entirely on the fact that the generic producers are potential competitors of the originator firm who is in possession of the patent. The concept of potential competitors and its boundaries has thus gained a pivotal role in the application of competition law to reverse payment agreements. Some of the guidance issued by the Commission specifies that potential competition exists when a company "*would be likely, on realistic grounds, to undertake the necessary additional investments*

1 D. Geradin, D. H. Ginsburg and G. Safty, Reverse Payment Patent Settlements in the European Union and the United States, *George Mason University Legal Studies Research Paper Series* LS 15–22, 2015, pp. 1–2.

2 D. H. Ginsburg and D. E. Haar, Resolving Conflicts between Competition and Other Values: The Roles of Courts and Other Institutions in the US and the EU, in P. Lowe and M. Marquis, *European Competition Annual 2012* (Hart, 2014), p. 426.

3 D. Geradin, et al., *supra* note 1.

4 Case CE/9742-13 *Unfair Pricing in Respect of the Supply of Phenytoin Sodium Capsules in the UK*, 7 December 2016.

5 Case *FTC v. Actavis, Inc.* (2013) 570 US, 133 S Ct 2223.

6 Case T-472/13 *H. Lundbeck A/S and Lundbeck Ltd v. European Commission* EU:T:2016:449.

7 Commission Decision, Case AT.39226 — *Lundbeck* C(2013) 3803 final.

8 CMA Press Release, CMA Fines Pharma Companies £45 Million, 12 February 2016.

9 M. McLennan, CMA: Pay-for-Delay Settlement "Restrictive in Its Own Right," *Global Competition Review*, 1 March 2017, online at http://globalcompetitionreview.com/article/1129399/cma-pay-for-delay-settlement-"restrictive-in-its-own-right"?utm_source=Law%20Business%20Research&utm_medium=email&utm_campaign=8060500_GCR%20Headlines%2001%2F03%2F2017&dm_i=1KSF,4SRIS,9GQ8I3,I2MUP,1.

10 CMA Press Release, CMA Alleges Anti-Competitive Agreements for Hydrocortisone Tablets, 3 March 2017.

or other necessary switching costs to enter the relevant product and geographic market(s) within a reasonably short period of time in response to a small and permanent increase in relative prices."[11] A purely theoretical possibility of entry would not suffice to sustain a finding of potential competition. In *Lundbeck*, the GC points to the specific reasons why, in this case, it considers generic producers to be potential competitors. In particular, it points out that it was not clear that their entry into the market before the expiration of the patent would "*undoubtedly* [have] *infringed the applicants' patents*," nor that these patents "*would certainly have withstood the claims of invalidity*" if the generic producers had indeed challenged them.[12]

6. The somewhat generous interpretation of the concept might undoubtedly prove helpful for effectively tackling arrangements which have the power to cause significant harm and which, should generic producers not qualify as potential competitors, would be virtually impossible to attack. However, the GC's position goes too far for some, and has already been subject to scholarly criticism. Ibáñez Colomo, for instance, wonders whether the notion of potential competition can really be stretched as far as to include situations in which a patent would have to be infringed in order to compete. He claims, shrewdly resorting to the paradox of Schrödinger's cat, that "*the position taken by the General Court is tantamount to saying that Schrödinger's cat is alive because it may be alive. A generic producer is a potential competitor, in other words, because it may successfully enter the market*."[13]

7. The controversy is served, and it is set to lead to a succulent discussion. In the context of this debate, the present paper brings together an exceptional panel of renowned experts in order to analyse the fascinating issues highlighted by the *Lundbeck* case in relation to the concept of potential competition. It begins with a thought-provoking contribution from Dr. Niamh Dunne of the School of Law of the London School of Economics exploring the logic behind the protection of future competitors, and engaging in a meticulous, critical assessment of the concept as envisaged by the European Commission and the European courts. Thereafter, Mr. Knut Fournier of Leiden University and the Hong Kong Competition Association provides a fresh, practical and comparative perspective by exploring the developments in the US in relation to the notion of potential competition. Professor Sofia O. Pais of the Portuguese Catholic University of Porto specifically covers the intersection between competition and patent law, that is, the paramount issues raised by *Lundbeck* relating to IP rights, and in particular in the light of Lemley and Shapiro's theory of probabilistic patents. Finally, Dr. Derek Ritzmann, Senior Vice President of Compass Lexecon Hong Kong and former Chief Economist of the Hong Kong Competition Commission, enriches the discussion by going beyond a purely legal analysis and giving his take on the recent EU developments through the lens of an economist.

8. I am extremely grateful to all of them for their excellent and timely contributions. Their pieces raise fundamental questions for the scholarly community to consider in relation to the boundaries of the concept of potential competition. The assorted views expressed in this article and the suggestions put forward make up a unique, outstanding ensemble, and I am delighted with the result of our joint effort. ■

11 *See*, for instance, Commission Notice — Guidelines on the Application of Article [101TFEU] to Technology Transfer Agreements (2004) OJ C 101/02, § 67.

12 GC's *Lundbeck* judgment, *supra* note 6, § 120.

13 P. Ibáñez Colomo, GC Judgment in Case T-472/13, Lundbeck v Commission: on Patents and Schrödinger's Cat, *Chillin' Competition* blog, 13 September 2016, online at https://chillingcompetition.com/2016/09/13/gc-judgment-in-case-t-47213-lundbeck-v-commission-on-patents-and-schrodingers-cat.

Why protect potential competition?

Niamh Dunne
n.m.dunne@lse.ac.uk
Assistant Professor, London School of Economics and Political Science

I. Introduction

1. "[T]*he art of playing a losing hand slowly*" is how pharmaceutical company Lundbeck described efforts to forestall generic competition following expiry of patent protection for its lucrative antidepressant, citalopram.[1] By "buying-off"[2] would-be rivals before they attempted entry, Lundbeck ensured that perceived potential competition failed to materialise into actual competitive challenges, thus resisting the downward pressure on prices that would have ensued. In doing so, however, it drew the ire of the European Commission, which condemned such blatant efforts to suppress expected future competition as a restriction by object contrary to Article 101(1) TFEU. This contribution explores the concept of potential competition, forefront in the *Lundbeck* decision and its appeal before the General Court, considering the rationale for and appropriate scope of the protection of prospective or nascent sources of competitive constraints within the broader framework of the EU competition rules.

2. EU competition law protects a myriad of (largely) complementary interests linked to the market process: of competitors, of customers, and furthermore of "*competition as such*."[3] Unsurprisingly, the notion of effective and free-functioning competition is integral to its various prohibitions. Broadly speaking, antitrust infringements can be divided between those which serve to exclude rivals, thus increasing the market power of remaining actors, and those which harness such power to exploit consumers directly. The concept of potential competition adds an additional complication to this broad dichotomy: to what extent should EU competition law furthermore peer into the future and concern itself with present conduct that might inhibit conceivable future competition that could—but not necessarily will—otherwise arise? Competition itself is an inherently dynamic process, premised upon constant cycles of market entry, exit and innovation. Yet the concept of potential competition is a somewhat contingent and hypothetical one, and thus presents a slippery target for antitrust enforcement. Disentangling the intrinsic from the purely speculative in the antitrust treatment of potential competition is thus the ultimate focus of this contribution.

II. Potential competition in and after *Lundbeck*

3. Potential competition is firmly established as a relevant parameter within the context of Article 101 TFEU. In scrutinising the conditions of competition within which any agreement is to be implemented, this assessment must be based: "*not only on existing competition between undertakings already present on the relevant market but also on potential competition, in order to ascertain whether* (…) *there are real concrete possibilities for the undertakings concerned to compete among themselves or for a new competitor to penetrate the relevant market and compete with the undertakings already established.*"[4]

4. To demonstrate such "real concrete possibilities,"[5] the likelihood of prospective competition must be more than "purely theoretical" and not "unrealistic."[6] Entry must therefore represent an "economically viable strategy" for the would-be competitor[7]—although, as *Lundbeck* illustrates, this requirement must be decoupled from the question of whether it might be more profitable to refrain from entry considering anticompetitive incentives to do so. A finding of potential competition does not depend, moreover, on any prior existence or absence of competition within the market; it is sufficient to demonstrate simply that there is scope for further competition.[8]

1 Commission Decision C(2013) 3803 final of 19 June 2013 relating to a proceeding under Article 101 [TFEU] and Article 53 of the EEA Agreement (Case AT.39226 — *Lundbeck*), § 187.

2 Case T-472/13 *H. Lundbeck A/S and Lundbeck Ltd v. European Commission* EU:T:2016:449 (hereafter "*Lundbeck*"), § 352.

3 *See*, e.g., Cases C-95/04 P *British Airways v. Commission* EU:C:2007:166, § 106; C-501/06 P *GlaxoSmithKline Services v. Commission* EU:C:2009:610, § 63; and T-461/07—*Visa Europe and Visa International Service v. Commission* EU:T:2011:181, § 126.

4 Case T-374/94 *European Night Services v. Commission* EU:T:1998:198, § 137.

5 *Lundbeck*, § 100.

6 *Visa*, § 85.

7 *Visa*, § 167; and *Lundbeck*, § 100.

8 *Visa*, §§ 128–131.

5. The key criterion is thus whether the potential competitor has an ability to enter the market; conversely, its intention to do so (or otherwise) is not determinative,[9] nor is it necessary to establish that entry would inevitably have been successful.[10] Accordingly, the crux of the notion is that, even absent a current presence on the market, the realistic possibility of new entry acts as a competitive constraint on existing actors.[11] The case law thus recognises that the present manifestation of potential competition "*may be no more than the existence of an undertaking outside that market*"—provided that that undertaking would be likely to enter the relevant market if it became a more attractive proposition in economic terms.[12] To qualify as a proximate source of competitive pressure, however, this necessarily implies that such entry could take place sufficiently quickly for the threat of potential entry to influence the conduct of incumbent market participants.[13]

6. Applying these principles in *Lundbeck*, the Commission held that "pay-to-delay" agreements with generic undertakings not yet present in the citalopram market constituted "by object" restrictions under Article 101(1) TFEU, insofar as the arrangements directly sought to prevent the competitive potential of those undertakings from being realised. The finding of potential competition thus hinged on the "dynamic competitive process" that is unleashed by the pending expiry of an active pharmaceutical ingredient (API) patent held by an originator undertaking.[14] This involves, *inter alia*, efforts to develop viable production processes for generic versions of the relevant medicinal product, to secure marketing authorisation, and to establish a distribution network, in a race to be "first to market" when generic entry becomes permissible.[15] The Commission's understanding of potential competition even extended to patent challenges and "at risk" entry which might prompt patent-infringement litigation, on the basis that such activities, although dubious from an IP law perspective, are part and parcel of the competitive landscape of the generic pharmaceuticals sector.[16] This finding was reinforced by the fact that generic undertakings had already made considerable investments in preparation for entering the citalopram market, prior to the impugned settlements.[17] Thus, generic undertakings were perceived as a competitive threat and thus exerted pressure on Lundbeck and other undertakings operating in the same market long prior to actual entry.[18]

7. Notably, the Commission supported its finding of potential competition by reference to the very fact that Lundbeck had concluded the impugned agreements with various would-be generic competitors precisely to avoid this perceived threat of entry.[19] The logic here might be criticised as somewhat circular, insofar as the mere existence of the suspect agreements apparently confirms their anticompetitive nature. Yet, intuitively, it is both plausible and pragmatic to infer from expensive and risky efforts to avoid even the prospect of a particular market outcome that there are significant vested interests at stake, and that the undertaking concerned has much to lose should the adverse result materialise. Moreover, the validity of the Commission's finding of potential competition was not undermined by the fact that it remained entirely possible that entry might not succeed in practice if, for instance, Lundbeck successfully deployed its process patents to exclude generic production.[20]

8. Given the significant consumer harm that can result from pay-to-delay arrangements—in, furthermore, a market context where public interest considerations extend beyond mere questions of efficiency[21]—this contribution does not dispute the ultimate finding in *Lundbeck* that the agreements constituted an anticompetitive restriction within the meaning of Article 101 TFEU. Nevertheless, the legal framing of the restrictive conduct at issue is remarkable for two reasons. First, the Commission treated the various settlements as by object restrictions, meaning that it was unnecessary to establish that they had the effect in practice of preventing or limiting potential competition from being realised. In so doing, it drew heavily on the precedent of the *BIDS* case, in which the Court of Justice accepted that a horizontal agreement to "buy-off" existing competition—accompanied by restraints intended to foreclose the potential for future new entry—constituted a restriction by object.[22] *Lundbeck* nonetheless represents a significant extension of the approach articulated in *BIDS* insofar as, with one limited exception, the counterparties to the pay-to-delay agreements did not yet compete in the markets concerned, nor was there any guarantee that entry, if attempted, would have been successful. As an object restriction, the buying-off of potential competition is therefore a step further removed from the existing competition process, and thus constitutes a rather more speculative or uncertain theory of harm.[23] The apparent prioritisation of potential competition within *Lundbeck* thus raises the question of why, and in what circumstances, an (essentially hypothetical) claim of potential competition ought to be protected, proactively, under competition law.

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9 *Lundbeck*, § 101.

10 *Lundbeck*, §§ 159 and 203.

11 *Visa*, § 189.

12 *Lundbeck*, § 102.

13 *Lundbeck*, § 104.

14 *Lundbeck*, § 93.

15 *Lundbeck*, §§ 92–95.

16 *Lundbeck*, §§ 96–97 and 128.

17 *Lundbeck*, §§ 124 and 131.

18 *Lundbeck*, § 144 and 163.

19 *Lundbeck*, §§ 103 and 181.

20 *Lundbeck*, § 203.

21 The broader context of pay-to-delay settlement is discussed in, e.g., European Commission, Pharmaceutical Sector Inquiry. Final Report, adopted 8 July 2009.

22 Case C-209/07 *Competition Authority v. Beef Industry Development Society (BIDS)* [2009] 4 CMLR 6.

23 Critiquing the "by object" approach in this context, *see*, e.g., S. Gallasch, Activating *Actavis* in Europe — The Proposal for a "Structured Effects-Based" Analysis for Pay-to-Delay Settlements, 36 *Legal Studies* 683, 2016, 688–693.

9. Second, the decision raises interesting questions with respect to the intersection between antitrust and intellectual property, and in particular, the manner in which the latter may inform or even predetermine the proper outcome of the competition process, and, consequently, the scope for potential competition. Notably, in *Lundbeck* both Commission and Court refused to accept that the mere existence of an IP right, the scope of which ostensibly encompasses the market activity subject to a claim of potential competition, is determinative of whether and to what extent such competition can be said to arise. Such an approach appears to have been heavily informed by the specific dynamics of competition within pharmaceutical markets, marked by bold and often risky behaviour by generic undertakings, alongside extensive and arguably excessive levels of patent protection granted to originators, particularly in respect of manufacturing processes. Yet, to hold that potential competition can exist even where its realisation would—or at least might—involve violation of validly maintained IP rights suggests a broad and, some might argue, overly ambitious understanding of the concept.[24] This, again, prompts questions regarding the nature and value of potential competition within the broader framework of the EU antitrust rules.

III. Explaining potential competition

10. All of which brings us to the core focus of this contribution—namely, the extent to which competition law can and should safeguard potential competition. On the one hand, protecting potential competition might be viewed as an indissociable component of the protection of "competition as such": the idea that markets should remain open and contestable, both to existing competitors and possible new entrants. Both Articles 101 and 102 TFEU consider not only the question of short-term competition but also longer-term implications of allegedly anticompetitive conduct;[25] the concept of potential competition is a necessary component of any such assessment. On the other hand, protection of potential competition might be viewed as the ultimate "*moving target*"[26] within antitrust, insofar as it requires undertakings to take account of the likely impact of their economic activity not only on existing rivals, but furthermore in terms of its possible effects on hypothetical future rivals. To the extent that EU competition law has been vulnerable to criticism, merited or otherwise, that it places undue emphasis on protection of competitors at the expense of broader considerations of consumer welfare, adding additional obligations towards possible prospective future rivals might be seen to add greater fuel to this fire. In what follows, we consider how the notion of potential competition aligns with and may be influenced by the general conceptual framework governing the EU antitrust rules, including questions regarding the nature of legitimate competition, the inherent uncertainty of the competition process, and the contemporary focus on efficiency-enhancing behaviour.

1. Competition on the merits

11. We begin with the nebulous notion of "*competition on the merits*,"[27] to be distinguished from "*methods different from those which condition normal competition*."[28] Competition on the merits may result in a prima facie diminution of potential competition, insofar as a highly competitive market may be less attractive to new entrants who perceive that there are fewer opportunities for profit to be made. At least in theory, however, "*competitors that are forced to exit the market due to fierce competition, rather than anticompetitive behaviour, are not protected*" by competition law.[29] The same logic (or scepticism) must obviously apply to potential competition. Prospective competitors dissuaded from entry where existing levels of competition are high should receive no protection under the competition rules to the extent that their complaint is, in essence, that the market structure results in a prioritisation of allocative over productive efficiency.

12. This conclusion is implicit in the treatment of potential competition in *Lundbeck*, where the court spoke in terms of a likelihood of entry "*if the market becomes more attractive*."[30] Where it becomes less attractive due to increasing levels of actual competition, the likelihood of entry decreases, and the competitive pressure exerted by ostensible potential competitors recedes. From an antitrust perspective, this diminution in overall competitive constraints within the marketplace is problematic only to the extent that entry has become less appealing due to "non-normal" methods of competition, whether resulting from collusion, such as the buying-off of potential competition at issue in *Lundbeck*, or from exclusionary unilateral conduct, where for instance the dominant undertaking raises barriers to entry by potential competitors. A lessening of potential competition is thus a concern for competition policy where it stems from artificial interference with the otherwise organic competition process: most obviously, where potential competitors are bullied or bribed by current market participants to refrain from entry. *Lundbeck* thus deployed the notion of "disproportionality" to separate permissible

24 *See*, e.g., R. Subiotto and J. Diaz, *Lundbeck v Commission*: Reverse Payment Patent Settlements as Restrictions of Competition by Object, 8 *Journal of European Competition Law & Practice* 27 (2017), 28, critiquing "*a lack of receptiveness to the specificities of the pharmaceutical industry, the importance of intellectual property rights, and the imperfect patent enforcement system*."

25 Reflected, for example, in the exemption for "technical progress" under Article 101(3) TFEU, and references to the balancing of incentives for innovation and investment in European Commission, Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings (OJ C 45/7, 24.2.2009) (hereafter "Enforcement Priorities"), §§ 75 and 87.

26 *Pacific Bell Telephone Co. v. linkLine Communications, Inc.*, 555 U.S. 438 (2009), Opinion of Roberts CJ.

27 Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v. European Commission* EU:C:2012:770, § 75.

28 Case C-85/76 *Hoffmann-La Roche & Co. AG v. Commission* EU:C:1979:36, § 91.

29 Opinion of Advocate General Wahl in Case C−413/14 P *Intel Corporation Inc. v. European Commission* EU:C:2016:788, § 41.

30 *Lundbeck*, § 102.

patent settlements from anticompetitive "pay-to-delay" arrangements,[31] language also found within the abuse of dominance case law.[32]

13. On the other hand, one of the more remarkable aspects of the *Lundbeck* decision is its apparent acceptance that potential competition, to be deserving of antitrust protection, need not need itself be meritorious as such. This follows from the finding that "at risk" entry—namely, where the generic undertaking launches a competing product in circumstances which arguably involve breach of the originator's IP rights—nonetheless constitutes "*the expression of potential competition*," at least where it has not yet been definitively established that the outstanding patent is infringed by the competing product.[33] Thus, contrary to the defendant's (admittedly self-serving) arguments in *Lundbeck*,[34] the protections of EU competition law are not restricted to unequivocally "lawful competition" as such. Any deliberate efforts to suppress potential competition are therefore likely to fall foul of Articles 101 or 102 TFEU, even if those would-be competitors might themselves encounter other legal hurdles to market participation should the anticipated competition in fact materialise.

2. Inherent uncertainty of the market process

14. A second relevant consideration is the concept inherent within EU competition law that "*each economic operator must determine independently the policy which it intends to adopt*" on the market.[35] This foundational tenet draws on the dynamic nature of the competition process, relying upon the spontaneous interaction of market actors to generate socially optimal outcomes. As the case law emphasises, this does not require that undertakings conduct themselves in a manner that is deliberately unmindful of the activities of other market participants, be they competitors or customers.[36] Indeed, such an approach would stand at odds with the fundamental underpinnings of the competition process, premised as it is upon intelligent adaption by market actors to the existing or anticipated conduct of competitors.[37] Competition law nonetheless seeks to proscribe and prevent behaviour that eliminates the risks and uncertainty inherent in the competitive process:[38] that is, conduct which seeks to replace the dynamism and unpredictability of the market mechanism with outcomes determined, in whole or part, through private ordering. This includes efforts to limit the possibility of new entry that may undermine the existing position of current market participants.

15. This concept has been well explored in the context of Article 101(1) TFEU, which is intended to prohibit any form of coordination which "*deliberately substitutes practical cooperation between undertakings for the risks of competition*."[39] This notion was central to the *BIDS* decision, in which the court effectively held that the proposed market reorganisation would permit remaining participants to reduce or even eliminate the competitive pressures exerted by current and potential future market actors.[40] Absent the impugned agreement, economies of scale could be realised only through merging—also subject to antitrust scrutiny—or intensifying of commercial rivalry.[41] With the BIDS agreement in place, however, those undertakings avoided the uncertainty and potential disruption of the competition process; and in particular, each eliminated the risk that it might, ultimately, prove to be one of the "losers" rather than successful "winners" emerging from that intrinsically unpredictable process.

16. As noted, this logic was extended in *Lundbeck* to cover horizontal agreements that expressly precluded entry by potential competitors.[42] The result, in those circumstances, was that the incumbent succeeded in heading off various credible competitive threats that could conceivably have challenged its established market position, which would, almost inevitably, have led to a fall in retail prices as Lundbeck responded to the increased competition generated by generic entry, whether legitimate or otherwise.[43] Although the General Court acknowledged that efforts to manage and minimise such uncertainty were understandable from a commercial perspective, it was at pains to emphasise that undertakings remain bound by the competition rules in so doing.[44] In particular, Lundbeck had essentially "bought" greater market stability through significant value transfers to potential competitors[45]—payments which corresponded not to the strength of the underlying patents in dispute, but rather to the profits anticipated by the generic undertakings if they had entered the market.[46] In this manner, both the Commission and Court concluded that Lundbeck was, in essence, seeking to prolong enjoyment

31 *Lundbeck*, § 354.

32 *See*, e.g., Case C-23/14 *Post Danmark A/S v. Konkurrencerådet (Post Danmark (II))* EU:C:2015:651, § 33.

33 *Lundbeck*, §§ 128–129.

34 *Lundbeck*, § 115.

35 *See*, e.g., Case C-40/73 *Coöperatieve Vereniging "Suiker Unie" UA and others v. Commission* EU:C:1975:174, § 173, and Case C-209/07 *Competition Authority v. Beef Industry Development Society Ltd and Barry Brothers (Carrigmore) Meats Ltd. (BIDS)* EU:C:2008:643, § 34.

36 *Suiker Unie*, § 174.

37 *Suiker Unie*, § 174.

38 Case C-48/69 *ICI v. Commission* EU:C:1972:70, § 112.

39 *BIDS*, § 34.

40 *BIDS*, §§ 33–35.

41 *BIDS*, § 35.

42 In particular, *Lundbeck*, § 424.

43 *Lundbeck*, §§ 377–385.

44 *Lundbeck*, §§ 377 and 380.

45 *Lundbeck*, § 382.

46 *Lundbeck*, § 354.

of its monopoly profit of "a quiet life"[47] by agreeing to transfer a portion of its actual monopoly profits to other undertakings in exchange for market abstention.[48]

17. This notion, that there is cause for antitrust concern where undertakings artificially limit the potential for future competition, finds parallels in other areas of competition law. The ability to forestall and thus avoid potential competition is an implicit component of the concept of dominance for the purposes of Article 102 TFEU, for instance. Per *Hoffmann-La Roche*, dominance reflects a position of economic strength pursuant to which the undertaking concerned can have "*an appreciable influence on the conditions under which* [any existing] *competition will develop*" on the relevant market.[49] Of course, dominance as such is not prohibited; yet its mere existence triggers a special responsibility, reflecting, *inter alia*, the heightened ability of the dominant undertaking to negatively affect current and future competition through exclusionary conduct.[50] Furthermore, although classification of the dominant undertaking as an "*unavoidable trading partner*" is premised primarily upon barriers to expansion which prevent existing competitors from increasing supply in the short term,[51] the same market features are likely in many instances to function as a barrier to entry by potential competitors.

18. Moreover, many of the theories of harm that arise under Article 102 TFEU have as an undercurrent the notion of artificially diminishing or restricting the inherent uncertainty of the competition process. The concept of abuse thus targets, *inter alia*, "*practices* [that] *tend to remove or restrict the buyer's freedom as regards choice of sources of supply,* [or] *to bar competitors from access to the market*."[52] These are, in effect, two sides of the same coin in terms of eliminating the uncertainty posed by the threat of potential competition: on the one hand, restricting the ability of consumers to switch to new competitors; on the other, restricting the ability of potential competitors to actually enter the marketplace.[53]

19. The antitrust treatment of so-called exclusivity rebates, whereby discounts are premised upon customers obtaining all or most of their requirements from the dominant undertaking, illustrates the role of market uncertainty here. Such rebates are, in effect, per se violations of Article 102 TFEU, on the basis that they are designed to remove or restrict the purchaser's freedom to choose his sources of supply and, accordingly, to deny other producers market access.[54] Of importance for our purposes is that such exclusionary effect is generated through the grant of a financial advantage, which induces customers to refrain from obtaining supplies from alternative providers.[55] In this manner, exclusivity rebates might similarly be viewed as a "buying-off" of competition, actual or potential, in a manner broadly equivalent to the pay-to-delay agreements at issue in *Lundbeck*; the key difference in the rebates context being that the exclusion of competition arises indirectly, insofar as customers have been, in effect, paid to avoid "shopping around."

20. Similarly, supply contracts with dominant firms that are excessive in scope and duration may breach Article 102 TFEU, where the effect is to make it more difficult for competing suppliers to acquire the dominant firm's customers.[56] Such practices may have a negative effect on both actual and potential competition—by hindering the ability of existing market players to expand their activities, but also making more difficult and thus deterring new entry, which limits levels of potential competition.[57] The anticompetitive motivation behind both exclusivity rebates and long-term contracts is thus essentially the same: by tying existing customers to the dominant undertaking for an extended period, and restricting their ability to switch to alternative providers, such practices substantially shrink the contestable portion of the market. The effect is to immunise the incumbent from actual and potential sources of competition, and thus attendant competitive constraints.

21. Finally, the case law on margin squeeze confirms that the exclusionary effects generated by such price-squeezing practices, and thus prohibited under Article 102 TFEU, extend to negative impacts on potential competitors.[58] In conducting the "as efficient competitor" analysis which lies at the heart of the legal test, the relevant costs are those incurred by the dominant undertaking,[59] an approach which clearly facilitates a finding of abuse even where potential competition fails to materialise into new entry. Margin squeeze, unlike the treatment of rebates or exclusive supply arrangements, does not represent the direct "buying-off" of competition as such. Yet, as the court acknowledged obliquely in *TeliaSonera*, it might be viewed as a deliberate limitation of commercial uncertainty in a manner not entirely dissimilar to that in *Lundbeck*. Specifically, given that the legal test for margin squeeze is premised upon a defendant's own costs and business strategy, that undertaking is expected to be aware of the negative impact that its pricing practices

47 *See* J. R. Hicks, Annual Survey of Economic Theory: The Theory of Monopoly, 3 *Econometrica* 1, 1935, 8.

48 *Lundbeck*, §§ 352 and 429.

49 *Hoffmann-La Roche*, § 39.

50 Case C-322/81 *NV Nederlandsche Banden Industrie Michelin v. Commission* EU:C:1983:313, § 10.

51 *Hoffmann-La Roche*, § 41.

52 C-280/08 P *Deutsche Telekom AG v. European Commission* EU:C:2010:603, § 175.

53 *See*, to this effect, *Post Danmark (II)*, § 31.

54 *Post Danmark (II)*, § 27; and Case T-286/09 *Intel Corp. v. European Commission* EU:T:2014:547, § 77.

55 *Intel*, § 77.

56 Commission Decision relating to a proceeding under Article 102 of the Treaty on the Functioning of the European Union and Article 54 of the EEA Agreement (Case COMP/39.386 — *Long-term contracts France*), published 17 March 2010.

57 Ibid., §§ 34–35.

58 Case C-52/09 *Konkurrensverket v. TeliaSonera Sverige AB* EU:C:2011:83, § 39.

59 *TeliaSonera*, §§ 41–42.

would have in terms of its own business model, absent vertical integration.[60] Consequently, it can be extrapolated from the setting of an unfair spread between wholesale and retail prices that the defendant should be aware of the anticompetitive potential of its actions. It might therefore be assumed that the defendant has deliberately acted to neutralise any competitive challenge downstream by maintaining such an unbalanced pricing structure, insofar as it is aware that profitable new entry is impossible.[61] The effect, much as in the case of pay-to-delay, is to curtail certain known sources of competitive constraint faced by the undertaking concerned, significantly reducing the likelihood, and thus the risk, that potential entry downstream will materialise or succeed.

3. Potential competition versus the "as-efficient" competitor

22. A third consideration is the extent to which protection of potential competition aligns with a contemporary focus on efficiency-enhancing behaviour. As Advocate General Wahl has observed, emphatically, "*given its economic character, competition law aims, in the final analysis, to enhance efficiency*."[62] Within the context of Article 102 TFEU, this is manifested in adoption of an "as-efficient competitor" (AEC) standard by which to assess the exclusionary impact of alleged abuses; the Commission states that it "*will normally only intervene where the conduct concerned has already been or is capable of hampering competition from competitors which are considered to be as efficient as the dominant undertaking*."[63] Limiting intervention to such circumstances aims to prioritise those situations in which the exclusionary effect of dominant behaviour has a concomitant negative impact on consumers, insofar as it is at least capable of excluding efficient (i.e., welfare-enhancing) sources of supply.[64] There is recognition, nonetheless, that participation by less efficient competitors may be beneficial in certain circumstances—and thus merits antitrust protection—including where the market structure makes emergence of any as-efficient competitor practically impossible,[65] or where a new entrant might benefit from network or learning effects which tend to enhance efficiency over time.[66]

23. At its core, the AEC analysis represents an acknowledgment that mere exclusion is not an exact synonym for consumer harm, and that it is the latter which forms the primary concern of competition law. All of which raises an important question regarding the nature of potential competition, and the extent to which it should be protected. The principal difficulty is that potential competition is inherently speculative. It represents incipient competitive forces which have not yet translated into actual commercial rivalry; accordingly, restricting potential competition does not deprive today's consumers of alternative sources of supply, although it may restrict the options available to tomorrow's consumers. Even that latter point remains somewhat notional, however; as discussed above, a finding of potential competition is not dependent upon any imminence of entry, or of any probability of success if entry is indeed attempted. Restriction of potential competition as an antitrust theory of harm is thus more difficult to reconcile with the general principle that "*the anti-competitive effect of a particular practice must not be purely hypothetical*" to justify intervention.[67] To put the point another way, why does potential competition merit antitrust protection where we struggle to say with certainty that it contributes to overall consumer welfare?

24. There are two ways of approaching this conceptual hurdle. The first would be to focus on the current contribution of potential rivals to competition within the relevant market. Implicit in the notion of potential competition as it emerges from *Lundbeck* is a perception on the part of incumbents that potential rivals pose at least a conceivable competitive threat, and that this external presence thus exerts competitive pressure on existing market players. Accordingly, even though the potential competitor may not contribute directly to increased efficiency, at the very least its presence constrains the market power of incumbent actors, and thus may serve to prevent "*behaviour which constitutes an expression of market power to the detriment of competition and, thus, to consumers.*"[68] An alternative approach is to focus on the nature and quality of the potential rival's future contribution to competition, if and when entry is attempted. From this perspective, bearing in mind the truism that commercial rivalry is not an end in itself, but serves to produce efficiency and thus promote consumer welfare, artificial obstacles to potential competition are problematic only insofar as they deny the market an equally efficient source of supply, unless circumstances suggest that a less efficient competitor would nonetheless make a valuable contribution to overall welfare.

25. Translating these distinct conceptual avenues to the approach in *Lundbeck*, we see the pay-to-delay settlements taking effect on the cusp between current and future understandings of potential competition. The rationale for these agreements, the case theory tells us, is that Lundbeck anticipated that the relevant counterparties would—imminently—attempt entry. Prior to expiry of the API patent, generic undertakings could not be conceived of as immediate potential competitors: the outstanding IP right definitively rendered entry unlawful. To the extent that Lundbeck felt potential competitive

60 *TeliaSonera*, §§ 42–45.

61 *TeliaSonera*, § 33.

62 Opinion in *Intel*, § 41.

63 Enforcement Priorities, § 23.

64 Opinion in *Intel*, § 42.

65 *Post Danmark (II)*, § 59.

66 Enforcement Priorities, § 24.

67 *Post Danmark (II)*, § 65. This approach can also be seen in the treatment of Article 101 TFEU in Case C-67/13 P *Groupement des cartes bancaires (CB) v. European Commission* EU:C:2014:2204, considered below.

68 Opinion in *Intel*, § 42.

constraints before that point, these were primarily exerted by other originator firms, which might develop superior medicinal products that would disrupt demand for citalopram. In the lead-up to expiry of the API patent, however, generic undertakings soon-to-be able to enter and compete within the citalopram market began to exert competitive pressure. At that point, the supra-competitive profits earned by Lundbeck served to invite entry, so that in order to maintain its existing market share going forward the incumbent operator either had to act in a more aggressively competitive manner—most obviously, by reducing prices—or, in order to minimise the threat posed by impending entry, in a more aggressively anti-competitive manner—in that instance, by concluding the impugned settlements.

26. Locating this understanding of potential competition within the framework of Article 101(1) TFEU, the Commission concluded that the pay-to-delay agreements had the object of restricting competition, making it unnecessary to consider whether they might have the effect of doing so in practice. This is, arguably, the most contentious element of the decision in *Lundbeck*. Designation as an object restriction effectively short-circuits the effects analysis that underpins the "*more economic approach*" to EU competition law.[69] It is thus, in principle, limited to forms of coordination that "*can be regarded, by their very nature, as being harmful to the proper functioning of normal competition.*"[70] That is, the impugned agreement must "*reveal a sufficient degree of harm to competition*" as such, so that "*there is no need to examine* [its] *effects*."[71] The difficulty here is that, although the Commission articulates a plausible theory of harm by which pay-to-delay agreements might diminish consumer welfare by prolonging monopoly pricing,[72] realising such harm in practice is contingent upon several antecedent assumptions: that entry would otherwise have been attempted, and would have succeeded in bringing down the market price. Yet, as we have seen, the definition of potential competition requires only "*real concrete possibilities*" for entry, as opposed to, for instance, any likelihood of success.[73] Thus, it might be considered that there is a disjuncture between the orthodox understanding of the object category and its application in *Lundbeck*, which calls into question the conclusion that such arrangements should be considered harmful "*by their very nature*." Such scepticism is reinforced by the approach of the Commission in the subsequent "pay-to-delay" case of *Servier*, in which it assessed broadly similar settlements as both object and effects-based restrictions of Article 101 TFEU—and, moreover, as abusive dominant behaviour contrary to Article 102 TFEU.[74]

27. Yet, the finding of an object restriction in *Lundbeck* is nonetheless compatible with the orthodoxy under Article 101(1) TFEU, and in particular, the renewed emphasis on assessing a suspect agreement in light of the "*content of its provisions, its objectives and the economic and legal context of which it forms a part*" following the *Cartes Bancaires* judgment.[75] In a sense, appraisal of the restraint in *Lundbeck* might be seen as the logical inverse of the conclusion in *Cartes Bancaires* itself.[76] In the latter, a prima facie restriction was held to (arguably) fall outside the "object box," given the significant efficiency justifications for the coordination when viewed in its specific economic context. Conversely, in *Lundbeck*, the legal and economic context served, in effect, to confirm the likelihood that these potentially restrictive arrangements would in fact harm competition. Relevant factors included the significant opportunities for market entry and thus upheaval created by expiry of the API patent,[77] the comparative weakness of Lundbeck's process patent,[78] and the likely impact of any attempted new entry on regulated drug prices at national level.[79] Moreover, although the subjective intention of the contracting parties is not determinative,[80] the fact that Lundbeck sought deliberately to ensure that potential competition would not translate into actual competition served to reinforce the conclusion that these agreements were inherently harmful to competition, even if the precise harm anticipated remained somewhat contingent or remote. The Commission could thus validly conclude that the impugned settlements were comparable to market exclusion agreements.[81] The specific market dynamics at issue accordingly rendered such deliberate efforts to subvert the competition process fundamentally suspect from an antitrust perspective, even in the absence of any direct link between the claimed potential competition and consumer welfare.

IV. Conclusion

28. Patent protection is wide-ranging yet temporary; the ostensible dichotomy it creates between monopoly and competition is sharp. Yet in its hinterland lies the spectre of potential competition, premised upon and activated by the market opportunities that result from inevitable expiry of the relevant IP right. As this contribution has discussed, the protection of potential competition has a particular pertinence in the context of pharmaceutical "pay-to-delay" settlements, where the supposed borderline between patent-protected monopoly and

69 *See*, e.g., A. Jones, Left Behind by Modernisation? Restrictions by Object under Article 101(1), 6 *European Law Journal* 649 (2010).

70 *Cartes Bancaires*, § 50.

71 *Cartes Bancaires*, § 49.

72 *Lundbeck*, § 386.

73 *See* note 4 above.

74 Commission Decision of 9 July 2014 in Case AT.39612 — *Perindopril (Servier)*.

75 *Cartes Bancaires*, § 53.

76 Contrast Gallasch (2016), 691, arguing that, post-*Cartes Bancaires*, the task of defending the "by object" treatment of pay-to-delay settlements "*has become a lot more difficult, if not insurmountable*."

77 *Lundbeck*, § 93.

78 *Lundbeck*, § 382.

79 *Lundbeck*, §§ 385–386.

80 *BIDS*, § 21.

81 *Lundbeck*, § 435.

open competition in fact accommodates a multiplicity of activities intended to realise—or, conversely, subvert—such competition in the future. Returning to the imagery which opened our discussion, patent holders inescapably hold a "losing hand" to the extent that any monopoly granted is time-limited yet the attendant publicity requirements are irreversible. Slow play via "pay-to-delay" may stave off the inevitable momentarily, yet it does so at the expense of consumer welfare and public budgets and, it might be argued, by upsetting the balance already struck within the patent system. Although at first glance perhaps somewhat conceptually problematic, therefore, the antitrust treatment of potential competition within the recent *Lundbeck* case in fact reflects a nuanced understanding of the interplay of competitive forces—actual and potential—within the market concerned.

29. Yet *Lundbeck*, and its consideration of potential competition, has resonance beyond the narrow context of its market circumstances. This contribution has sought to illustrate and analyse the extent to which the concept has a grounding within the framework of EU competition law, and moreover, the manner in which its protection might be reconciled with our current preoccupation with "more economic" approaches to antitrust analysis. Protection of potential competition must negotiate a difficult path: between healthy scepticism of unduly speculative theories of harm which might prompt false positives, on the one hand, and the dynamic nature of the competition process on the other, premised upon contestable markets and creative destruction. *Lundbeck* provides a convincing, though not unassailable, defence of the latter, confirming the central importance of potential competition, particularly in markets where actual competition is substantially curtailed. The wider application of this comparatively expansive understanding of potential competition remains, however, to be seen. ■

The notion of "potential competitor" in US antitrust enforcement: Pragmatism and legal certainty

Knut Fournier
knut.fournier@gmail.com
PhD Candidate, Leiden University,
Chairperson, Hong Kong Competition Association

I. Introduction

1. This article explores the state of the law on pay-for-delay agreements in the US. It also presents an opportunity, in the context of the present series of articles, to compare the approach in the US with the EU case law with regards to the notion of potential competitor, which has crystallised a large swath of the *Lundbeck* debate in the EU.[1] This approach, outlined below in three sections, reveals fundamental differences between US cases, in which very little attention was given to whether parties were competing or not, and the European Commission/GC debate, which focussed heavily on this issue. This article argues that the notion of potential competitor has been given excessive amounts of attention by EU enforcers and courts, due to reliance on precedents which were not related to pay-for-delay agreements. It purports to highlight the advantages of the US approach to assessing reverse patent settlements.

2. The debate over the notion of potential competitor did not happen in a vacuum. It developed at a very particular time for antitrust enforcement, when a growing focus on new technologies, IP issues and innovation forces regulators to think increasingly in terms of what the market could look like in a couple of years. The question of whether competition authorities and courts should look at future markets, and to what extent, is of course at the heart of today's multiple debates concerning the interaction of antitrust and innovation. As the present article discusses below, the notion of potential competitor took off in US antitrust in the *U.S. v. Microsoft* judgment, further highlighting that competitive dynamics are more complex in innovation-linked markets. This fundamental link between innovation and the notion of potential competitor means that the issue is likely to resurface, given the importance of IP issue and innovation-related questions in today's antitrust landscape.

3. This article begins with a first section on the state of the law on pay-for-delay agreements in the US, including the legislative and regulatory framework surrounding the approval of generic drugs. The second part discusses how the notion of potential competitor was approached in a merger context, where it is more developed than in antitrust enforcement. The third part looks at Sherman Act enforcement, including in pay-for-delay cases and in the *U.S. v. Microsoft* judgment. The fourth part argues that the reason why the notion of potential competitor is not a central factor in pay-for-delay enforcement is that US courts and enforcers have found pragmatic and reasonable approaches to the issue, resulting in heightened legal certainty in the pharmaceutical industry.

II. The state of antitrust enforcement and pay-for-delay agreements under US law

4. In the history of pay-for-delay enforcement, there is a before and after *Actavis*. In the *Federal Trade Commission v. Actavis Inc.*[2] case, the Supreme Court of the United States confirmed that the FTC could investigate

1 *See* the EC ruling: European Commission, *Lundbeck*, Case AT.39226, 19 June 2013; and the General Court decision: General Court (Ninth Chamber), *H. Lundbeck A/S and Lundbeck Ltd v. European Commission*, Case T-472/13, 8 September 2016.

2 *FTC v. Actavis, Inc.*, 570 U.S. ___, 133 S. Ct. 2223 (2013).

"*reverse payment*" or "*reverse settlement*" agreements. The Supreme Court reversed the District Court and the Circuit Court, and said that the fact that these agreements were framed as dispute settlement agreements, or intellectual property agreements, did not prevent the enforcement of antitrust laws against them. It stopped short of qualifying reverse patent settlements per se anticompetitive, and instead directed the courts to use a rule-of-reason approach.

5. Before looking at the impact of *Actavis* on US antitrust enforcement, it is necessary to understand the normative background in which the decision took place. Prior to 1984, the only way for manufacturers of generic drugs (hereinafter "generic manufacturers") to put new drugs on the market was to introduce them the same way drug originators did: by filing a new drug application. Generic manufacturer applicants were required to submit safety and efficacy tests as part of their application, regardless of whether such tests had already been performed for similar components for the original drug, prior to its approval. This triggered two types of issues: first, a new drug application is an expensive and cumbersome process, and undergoing studies which have already been completed was inefficient. Second, performing such studies could have infringed the patent of the drug originator and therefore exposed the generic manufacturer to patent litigation. Congress, in a move to spur more generic applications, passed the Drug Price Competition and Patent Term Restoration Act, or "Hatch-Waxman" Act ("the Act"), in 1984. The principal measure of the Act is to create a second track for drug approval, specifically aimed at generic manufacturers: the abbreviated new drug application (ANDA). An ANDA allows an applicant to rely on the safety and efficacy studies previously filed by the drug originator.[3] To further facilitate the introduction of generics, the Act clarifies that such use of the drug originator's studies does not constitute a patent infringement.

6. The Act makes information accessible for generic manufacturers to facilitate entry: drug originators are required, when applying for a new drug approval, to submit to the Food and Drug Administration (FDA) the patent numbers and expiration dates of any patents which a generic manufacturer may infringe. This information is publicised by the FDA, in what is colloquially known as the Orange Book. Generic manufacturers who file for an ANDA must make one of the four following certifications: first, that the patent information was not filed by the drug originator was not filed by the FDA; second, that the patent is expired; third, that the patent will expire soon; or fourth that the patent is invalid, or that the method chosen by the generic manufacturer to manufacture, use, or sell the drug will not infringe the patent. The first and the second options merit little comment, as these essentially mean that there will be no conflict between the two actors. In the third option, the FDA cannot grant approval of the generic before the expiry of the patent. The fourth option, commonly known as a "paragraph IV certification," is the course of events in which antitrust lawyers will be most interested. Under the Act, the applicant must notify the patent holder. The notification opens a 45-day window for the patent holder to file suit for infringement. If such a suit is filed, the ANDA approval is automatically delayed by thirty months. This delay terminates if the court hearing the infringement suit declares the patent invalid or not infringed. If the court rules in favour of the patent holder, the ANDA approval is set for a date after the expiry of the patent. If competing generic manufacturers file multiple ANDA applications for a single drug, the Act provides a strong incentive for generic manufacturers to try and be "first in line," as the successful first applicant is granted a 180-day exclusivity period following the approval of the generic drug.

7. Reverse patent settlement agreements, or "pay-for-delay" agreements, take place in this regulatory and legislative context. The drug originator, having been warned by the generic manufacturer itself (remember that a notification is mandatory under the Act), enters into negotiations with the generic manufacturer, for instance during the patent infringement suit which ensues the ANDA application. When the drug originator pays or otherwise compensates the generic manufacturer to stay out of the market for this particular drug, this settlement agreement may infringe Section 1 of the Sherman Act. Since the 2013 *Actavis* case, which confirmed that antitrust enforcement was possible against these agreements no matter how these were framed, the debate has shifted. In two recent significant decisions, two circuit courts of appeal confirmed that the absence of a cash payment did not bar antitrust enforcement against a reverse patent settlement.[4] One of these two decisions, by the Third Circuit, is currently pending appeal to the Supreme Court, which has not yet announced whether it will grant certiorari. The reason for the relative uncertainty around non-cash settlements is the language of the *Actavis* ruling, which refers to "large unexplained payments." It may have been a no-brainer that non-cash settlements may too violate antitrust laws. Yet the *Actavis* ruling, as many others in recent years, saw a court divided along partisan lines (5-3, with Roberts, Scalia and Thomas dissenting, and Alito recusing himself). Therefore, the uncertainty remains.

8. The Act has at least partially achieved its goals in that it greatly increased the share of generics prescribed in the US. However, it is also criticised, by academics and by the courts, for having created incentives to collude. Justice Breyer, writing for the Supreme Court in *Actavis*, noted that it was unusual for patentees to settle with challengers, since this could attract a flurry of other litigants. It may be, as Justice Breyer noted, that the 180-day delay included in the Act for any successful generic manufacturer who was not the first applicant may explain why in generic drug application-related litigation, the fear of attracting more litigants did not seem to play such a restraint on the patentee's incentive

3 21 U.S.C. 355(j).

4 *See Loestrin 24 Fe Antitrust Litigation*, No. 14-2071 and 15-1250 (1st Cir.) and *King Drug Company of Florence Inc. v. Smithkline Beecham Corporation*, No. 14-1243 (3rd Cir.).

to settle. An additional possible criticism of the Act is that the relatively open and transparent mechanism of the Orange Book clearly signals to drug originators where the competition is coming from. The applicant who files a paragraph IV certification certainly loses the benefits of any surprise effect, but it also puts the two actors on track for a collusion in court, which is all too tempting to resolve by a settlement. There does not seem to have been any study focussed on the costs and benefits of the relative transparency of the Orange Book mechanism, versus a system in which generic manufacturers do not have to reveal their plans until, for instance, shortly before the drug is put on the market. It seems, at least intuitively, that this would shorten the time period available for drug originators and generic manufacturers to engage in reverse patent settlements—although this may run against public policy, which favours the settlement of disputes.

III. Potential competitor in a merger context

9. The surprising element of the US regulatory and case law background to pay-for-delay settlements is, for the EU lawyer, its relative simplicity. One may believe that in a system in which antitrust law enforcement is often criminal, and where the courts welcome direct action by plaintiffs, the law would become daedalian, but the mere 20 pages of Justice Breyer's opinion in *Actavis* strike by their brevity. This contrasts with the 847 paragraphs of the General Court of the EU's ruling in *Lundbeck*, upholding the 464-page Commission decision, of which nearly 170 are dedicated to the issue of "potential competitor." This article is not the place to discuss the merits of simplicity in judicial decisions, but there is value in trying to determine whether such focus, in the EU approach, is beneficial to the parties, to the pharmaceutical industry and even to the antitrust community, who must now adjust their practices and advice based on the *Lundbeck* principles. In short, one must ask whether such a debate advances the law at all, and the comparison with the US approach might help to answer this question.

1. The potential competitor doctrine as an enforcement sword

10. In contrast, the US potential competitor doctrine has evolved in three phases, resulting in a settled approach which is no longer the subject of the debates it once was, and certainly not the debates seen in the EU in the *Lundbeck* context. The framework is somehow different, however, since the potential competitor doctrine primarily developed in a merger control context, and it remains a predominantly merger-related concept today. In a merger context, potential competitors are a neighbouring notion to the idea of "market entry," which in turn raises issues of barrier to entry. However, the development of the potential competitor doctrine in the US took place at a very particular time: in the 1960s and 1970s. Anti-merger sentiment was rife among regulators at that time, and the fear of what was perceived as ever-growing conglomerates led to numerous enforcement actions against planned mergers. Because of the context in which the doctrine developed, its relevance to today's competition enforcement is limited, and the test as it evolved has not been applied outside of merger control.

11. The potential competitor doctrine has been one of the very creative theories of harm developed by enforcers and by the courts in the 1960s, when the fear of conglomerates led to an aggressive period of merger enforcement, resulting in multiple combinations which were blocked or which settled with remedies—cases which would probably not have met the same fate today. In particular, two Supreme Court decisions crystallised the concept, with strong anti-merger sentiments in the background and serious consequences ensuing. In *United States v. Penn-Olin Chemicals Co.*,[5] the Supreme Court in 1964 reversed the District Court decision which had allowed two companies to form a joint venture. It held that "[t]*he test of whether a joint venture might substantially lessen competition within the meaning of* [Section] *7* [of the Clayton Act] *is not only whether both parent companies would probably have entered the market, or whether one would probably have entered alone, but also whether the joint venture eliminated the potential competition of the company that might have stayed at the edge of the market, threatening to enter*."[6]

12. The parties had entered into a joint venture to enter into a new market, and the DOJ was seeking to block the concentration despite the absence of evidence that either of the parties was planning to individually enter this new market. The court ruled that Section 7 of the Clayton Act was concerned with "*probabilities, no certainties*."[7] This added the concept of the elimination of a threatening competitor; to the already long list of theories of harm pursued by the DOJ in its crusade against mergers and perceived conglomerates. This potential competition theory was then applied in the 1967 infamous *FTC v. Procter & Gamble Co.*,[8] in which the court empowered the FTC to block P&G's acquisition of a household bleach maker. The Supreme Court, reflecting the language of its earlier decision in *Penn-Olin*, agreed with the FTC that P&G was "*at the edge of the industry*."[9] There was scant evidence that P&G would have entered the market absent an acquisition, but it remained, for the agency, the "*most likely entrant*."[10]

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5 *United States v. Penn-Olin Chemical Co.* 378 U.S. 158 (1964).

6 Ibid., at 173–174.

7 Ibid., at 182.

8 *FTC v. Procter & Gamble Co.* 386 U.S. 568 (1967).

9 Ibid., at 581.

10 Ibid.

13. The theory focussed on "perceived" potential competition was then a tool to block mergers and concentrations, but it soon bent under the weight of the Chicago School of economics. Prior to the spread of Chicago School ideas, the theory was that a perceived potential entrant would already influence the market, and incumbents will charge below monopoly prices in order to deter entry. The next two decades saw the "perceived" potential competition theory, and in particular the idea of a disciplinary effect of potential entrants on prices, retreat under court decisions imposing higher standards of proof on agencies and requiring evidence of "actual" plans to enter the market. This shift built on the fact that there was limited empirical evidence to support the idea that the pressure exercised by a potential entrant was comparable to the pricing limit effect of actual competition.[11] The FTC lost a string of cases and was subsequently required to provide proof of active steps towards entry or, absent such evidence, some other objective evidence that entry was likely.[12] The actual potential entry; thus gradually took shape, slowly raising the bar of the reasonable probability of entry; standard of the 1960s.[13]

2. The potential competitor doctrine as a shield against enforcement

14. The economic rationale behind perceived potential competition is that the market behaviour of actors is influenced not only by current market players, but also by potential market players. Consequently, this can play both ways in antitrust disputes. Turning the argument around, companies seeking to merge can invoke potential entrants as a defence: this is the "ease of entry" defence. Because the economic theory purports that a monopoly may not charge monopoly prices if entry is so easy that monopoly prices would attract new entrants—merging parties accused or suspected of seeking monopoly power turned the argument around to claim that potential entrants would limit their market power. In the 1980s, despite the controversies surrounding the theoretical basis for this defence, the Department of Justice (DOJ) lost a series of merger challenges in court, based on low barriers to entry.[14] In each case, the arguments developed by agencies to support potential competition as a theory of harm were used by the merging firms to justify transactions that would lead to high levels of concentrations. The DOJ attempted to rebut the evidence, alleging that there was no proof that entry would take place in the short term, or that it would put pressure on the incumbents. The court replied, flipping the argument around, that Section 7 was concerned with "*probabilities, no certainties*."

11 L. A. Sullivan, W. S. Grimes and C. L. Sagers, *The Law of Antitrust* (West Academic Publishing, 2016), 561.

12 *See*, for instance, *Tenneco, Inc., Petitioner, v. FTC*, 689 F.2d 346 (2d Cir. 1982).

13 For a rare Supreme Court decision discussing the "perceived potential competitor" theory, and rejecting an FTC complaint on the basis that the agency had not met its burden of proof, *see*: *United States v. Marine Bancorporation, Inc.* 418 U.S. 602 (1974).

14 *United States v. Waste Management, Inc*. 743 F.2d 976 (2d Cir. 1984). *See also United States v. Baker Hughes*, 908 F.2d 981 (D.C.Circ. 1990).

IV. "Potential competitor" in Sherman Act enforcement

15. The notion of potential competitor in US laws is almost absent from US antitrust enforcement. The Sherman Act does not mention "potential competitors." In the FTC and DOJ's Antitrust Guidelines for Collaboration Among Competitors, the notion is expedited as early as page 2, in a footnote which reads: "*Firms also may be in a buyer-seller or other relationship, but that does not eliminate the need to examine the competitor relationship, if present. A firm is treated as a potential competitor if there is evidence that entry by that firm is reasonably probable in the absence of the relevant agreement, or that competitively significant decisions by actual competitors are constrained by concerns that anticompetitive conduct likely would induce the firm to enter*."

16. The most high-profile and most detailed discussion of potential competition in an antitrust context is found in the *U.S. v. Microsoft* judgment.[15] The argument appears when Microsoft contends that the government did not sufficiently prove causation (i.e., that its anticompetitive conduct was not caused by its monopoly power). The court counters by inferring causation when Microsoft's conduct appears reasonably capable of making a contribution to its monopoly power. Since the court found that the actions of Microsoft were directed as "nascent competitors," it feels compelled to explain that even against newly established competitors, exclusionary conduct against these nascent competitors can be sufficient to infer causation. This passage of the *Microsoft* decision therefore deals with a different type of potential competitor than those discussed above under merger control rules, and those referred to at such length in the decisions of the Commission and the GC, in which competitors have not yet entered the market. Nonetheless, the *Microsoft* passage highlights the limitations of courts and agencies in dealing with events which have not yet happened.

17. These passages crystallise the very deficiencies of antitrust rules (and legal rules in general) in dealing with fast-moving markets and innovative products, which are characterised by a high degree of uncertainty. Yet, the passage also demonstrates the court's ingenuity in assembling antithetic concepts such as "causation" and "uncertainty." The DC Circuit court begins by dismissing the idea that it must adhere to the traditional "causation" test, which is, in the traditional verbose style of the DC Circuit, "edentulous." Rather, the court finds two questions to answer. First, whether in general the elimination of nascent threats is "*reasonably capable of*

15 *United States v. Microsoft Corporation* 253 F.3d 34 (D.C. Cir. 2001).

contributing significantly to a defendant's continued monopoly power."[16] The court finds that the Sherman Act's purpose is well served by ensuring that monopolists do not have free reign in quashing "*nascent, albeit unproven, competitors at will—particularly in industries marked by rapid technological advance and frequent paradigm shifts*."[17] Second, the court must determine whether the parties excluded in this case "*reasonably constituted nascent threats*."[18] This point was conceded by Microsoft itself during oral arguments, and therefore Microsoft was found to be increasing its monopoly power when it excluded Java and Netscape, two nascent developers of software applications. This is controversial: the same Navigator and Java had been, in the same decision, eliminated from the market definition (thus allowing for the government to successfully frame Microsoft as a monopoly) on the basis that the effect of Navigator and Java's entry on the market was not reasonably foreseeable, and would only take place in "several years." The court found no contradiction in this, and confirmed that there was truly under the law a double standard regarding potential entrant as a threat, and potential entrant as a competitive pressure acting as a check on a monopolist. The difference, the court argued, lies in the language of Section 2 of the Sherman Act, which allows for enforcement against exclusionary behaviour targeted at nascent threats (or rather did not prohibit it), and the exercise of market definition which is focussed on identifying products which are readily (i.e., currently) substitutable.

18. Looking past this questionable double standard, the interesting focus here is on the perception by the defendant itself of who its potential competitors are. Through discovery, depositions and cross-examination, if company B truly poses a threat to company A, a well-mounted litigation strategy should be able to uncover a document, an email, or a power point which records this fear, or it should be able to find someone to testify of the company's perception. This emphasis on the company's perception at least as a matter of proof, and its simplicity, rely on well-established processes of discovery and on the ability to cross-examine witnesses under oath and in an open court. The benefits of such features of a legal system are innumerable. Looking at the question of the level of proof in relation to potential competition, such a trust in the strength of the litigation tools is also found in the FTC practice, which said in 1980 about finding subjective evidence of intention to enter a market: "*It will often be difficult to secure such evidence. Nevertheless, if the firm's intention to enter independently has become sufficiently concrete to warrant the preparation of capital budgets and other actual steps toward entry, that intention will ordinarily be memorialized in one documentary form or another*."[19]

16 Ibid., p. 79.

17 Ibid.

18 Ibid.

19 FTC, *Opinion of the Commission in the matter of B.A.T. Industries, Ltd., and Appleton Papers, Inc.*, 104 FTC, 852 (1984), p. 916.

V. Conclusion: Why the notion of potential competitor is not a factor in pay-for-delay litigation

19. As said above and in the *Actavis* case, one of the flaws of the Act is its tendency to allow drug originators and generic manufacturers to easily find each other, possibly resulting in reverse patent settlements. However, for the enforcers and the courts, this has turned into an advantage: the ANDA approval process, which requires the generic manufacturer to file with the FDA and to notify the patent holder at the same time, clearly identifies the potential competitors.

20. This was not the intention of Congress, just as it was not the intention of Congress to increase pharmaceutical companies' incentives to collude, but it results from this regulatory set-up that there is little doubt left about who is a threat to whom. Generic manufacturers are required by law to write to the patent holder and essentially tell them: "*I intend to put a similar drug on the market*." There is no space in the US framework for the argument raised by the parties in the EU *Lundbeck* case, i.e., that they were not competitors at the time of the agreement and that therefore the agreement is not anticompetitive.

21. However, this is not to say that US courts in pay-for-delay litigation are not concerned with who does what, and where companies sit vis-à-vis each other. Actavis and Paddock, the respondents, were potential competitors to Solvay, since they filed applications saying essentially this. The pragmatism of the court is to be lauded: it is not a possible option for the parties to challenge this reality. The reason is not that the regulatory framework was fundamentally different than in the EU *Lundbeck* case. It was not. The argument was not raised because it would have made no sense. Justice Breyer ruled that a large, unexplained payment is sufficient to show that there are doubts about the survival of the patent. The corollary to this is that a large unexplained payment is sufficient to prove that Solvay believed that the respondents were a credible threat to Solvay's revenue line. In other pay-for-delay cases, including cases pre-*Actavis*, the issue of potential competition is generally accorded one paragraph. For instance, in *Drug Valley Company*, a case about hypertension drugs, the 11th Circuit Court of Appeals noted that "*on the eve of the agreement, both Geneva and Zenith were poised to market generic versions of Hytrin in the United States*."[20]

20 *Valley Drug Company, Louisiana Wholesale Drug Company, Inc., et al., v. Geneva Pharmaceuticals, Inc., Abbott Laboratories*, 344 F.3d 1294 (11th Cir. 2003).

22. To have entertained, as the General Court did in *Lundbeck*, the parties' argument that competition law did not apply to them because they were not, at the time of the agreement, potential competitors, is doing everyone a disservice. The parties presumably have spent staggering amounts of time and money mounting this argument, with little chances of success. The General Court spent resources writing a mind-numbing 330 paragraphs to confirm that yes, drug originators and generic manufacturers who entered into a multi-million-dollar agreement are indeed potential competitors. This has now been appealed, including on the ground that the court erred on finding that the parties were potential competitors.[21] The Commission's decision to entertain the argument, and the General Court's willingness to debate it seem to be founded on vaguely related precedents.[22] By no stretch of the imagination could these precedents have called for a tedious justification of the obvious.

23. In conclusion, the comparison of the US and the EU approach on potential competition reveals that the US has developed a solid and simple presumption: that a large, unexplained payment is sufficient to show that there are doubts about the survival of the patent. This presumption could be applied to the notion of potential competitor in the EU, thus resulting in improved legal security and certainty. This would free resources on all sides to focus on issues which truly deserve this level of attention. ■

21 *See*, for instance, for one of the six notices of appeal: Case C-591/16 P: Appeal brought on 18 November 2016 by H. Lundbeck A/S, Lundbeck Ltd against the judgment of the General Court (Ninth Chamber) delivered on 8 September 2016 in Case T-472/13 *H. Lundbeck A/S, Lundbeck Ltd v. European Commission*.

22 Joined-Cases T-374/94, T-375/94, T-384/94 and T-388/94, *European Night Services and Others v. Commission* [1998] ECR II-3141; and Case T-461/07 *Visa Europe Ltd and Visa International Service v. European Commission*, 14 April 2011.

The *Lundbeck* case through the lens of probabilistic patents

Sofia Oliveira Pais
spais@porto.ucp.pt
Professor of Law, Faculdade de Direito-Porto, Universidade Católica Portuguesa, and Jean Monnet Chair

I. Introduction: Pay-for-delay agreements and the balance between patent law and competition law

1. Pay-for-delay agreements, or patent settlement agreements with reverse payment, are agreements concluded between the holder of the patent (originator firm) and the generic supplier in the pharmaceutical industry. They are entered into before the date of the expiry of the patent to avoid litigation concerning the validity of the patent and may involve 'agreed entry dates' and the 'transfer of value' to the generic firm. In addition, they may also cover the delay of the entry of the generic version of the patented drug into the market after the expiry of the patent in which case they clearly infringe antitrust rules. Although patent settlement agreements can save cost and time, and promote innovation, they might also raise antitrust concerns. For instance, the prices of the drugs may increase, since the monopoly of the former patent holder is preserved. Consumers may be harmed and innovation hindered.[1] Scrutinising the effects of patent settlements with reverse payments is clearly relevant from a consumer welfare perspective, so that the effects of the conduct in prices and innovation may be monitored by antitrust authorities. Moreover, such arrangements also have significant implications for the application of patent law. In particular, issues might arise in the context of so-called "weak patents"—that is, those patents that might not be indisputably invalid, "*but nobody knows for sure without conclusive litigation*."[2] In fact, it has been pointed out that patent settlements with large reverse payments will only occur where weak patents exist.[3] Both the consumer welfare and patent law dimensions should, therefore, be considered closely linked in the analysis of this type of agreements.

2. The study of patent settlements in the pharmaceutical industry cannot ignore the evidence that suggests that patents are sometimes granted erroneously. While only a small number of patents—about 0.1%—is challenged in court, of those that are challenged around 50% are deemed to be invalid in patent litigation.[4] Such statistics encourage the patent holder to settle if its patent is indeed facing legal action.[5] These patent settlements may have the positive effect of avoiding litigation costs, but they may also create barriers to market entry and hinder competition.

3. The majority of scholars argue that pay-for-delay agreements must be assessed under competition law. However, there is no consensus as to the most adequate legal solution. Some advocate for a presumption of illegality for pay-for-delay agreements,[6] while others argue that they should be per se illegal.[7] Some voices defend analysing them under the rule of reason,[8] and there are

1 For an analysis of the contrasting approaches taken in the EU and in the USA with regard to reverse patent settlement agreements, *see* D. Geradin, D. Ginsburg and G. Safty, Reverse Payment Patent Settlements in the European Union and the United States, *George Mason University Legal Studies Research Paper Series* LS 15–22, 2015. *See also* W. Choi, B. den Uyl and M. Hughes, Pay-for-Delay Practices in the Pharmaceutical Sector: Lundbeck, Actavis, and Others, 5(1) *Journal of European Competition Law & Practice*, 2014, 44.

2 J. Farrell and C. Shapiro, How Strong are Weak Patents? 98 *American Economic Review* 4, 2008, 1347–1369, at p. 1347.

3 *See* W. Kerber and S. Frank, Patent Settlements in the Pharmaceutical Industry: What Can We Learn from Economic Analysis? *Philipps-Universität Marburg, MACIE Paper Series*, No. 2016/1, p. 2.

4 Furthermore, it has been argued that proving validity and infringement is more difficult for process claims, *see*, for example, O. Zafar, Lundbeck, and Johnson & Johnson and Novartis: The European Commission's 2013 "Pay-for-Delay" Decisions, 5(4), *Journal of European Competition Law & Practice*, 2014, p. 207.

5 As Kerber and Frank pointed out, "*from an economic perspective, policy solutions for the weak patent problem in competition law and in patent law are alternative options*."Kerber and Frank (2016) above, p. 26

6 *See* H. Hovenkamp et al., *IP and Antitrust*, 2d ed. (Wolters Kluwer, 2010) § 15.3a1(C).

7 M. A. O'Rourke and J. F. Brodley, An Incentives Approach to Patent Settlements, 87 *Minnesota Law Review*, 2003, p. 1767.

8 R. D. Blair and T. F. Cotter, Are Settlements of Patent Disputes Illegal per Se? 47 *Antitrust Bulletin*, 2002, p. 491.

also those scholars who propose the application of a structured effects-based approach instead of considering those agreements restrictions by object.[9] The difficulties in striking the right balance between the interests of patent law—in increasing the incentives given to pharmaceutical firms to innovate—and the interests of competition law—in avoiding consumer harm—are, therefore, particularly visible in this kind of agreements.

4. The goal of this article is to analyse the *Lundbeck* case through the lens of probabilistic patent rights theory. As stressed above, the actual scope of a patent right, its commercial value and its validity are contingent questions. These uncertainties are an inherent part of the patent system and require rethinking not only several of the solutions offered by patent law, but also the limits of competition law when it comes to patent settlements. The purpose here is to reflect on the new approach followed by the GC in the *Lundbeck* case, taking into account the theory of probabilistic patent rights. The article first explores the essentials of probabilistic patents theory (II.). It then goes on to discuss the *Lundbeck* case (III.), and the concept of potential competitor that the GC seems to adhere to (IV.). Subsequently, the judgment is placed in the context of previous developments in the EU and US relating to the concept of potential competitors (V.), and conclusions are drawn (VI.).

II. The theory of probabilistic patents explained

5. The uncertainties as to the commercial significance of patents and as to their validity have been clearly stressed by Mark Lemley and Carl Shapiro in the theory of probabilistic patent rights. They challenge the traditional view that sees patents as well-defined property rights giving their owners a monopoly over a market and competitive advantages. According to the conventional position, once issued patents should be presumed valid, and the owner could, therefore, exclude rivals. Moreover, patents would be issued without engaging in extensive evaluation, which would increase the likelihood of invalidity and put into question the commercial value of the patents. Taking into account these uncertainties, the authors concluded that a "*patent does not confer upon its owner the right to exclude but rather a right to try to exclude*."[10] The patent legal framework would thus encourage firms to settle either using reverse payments or other solutions. Among the latter would be licensing agreements with small royalties, for instance. Since some of these agreements should be presumed anticompetitive, particularly patent settlements with large reverse payments, probabilistic patent rights theory suggests that antitrust limits on these settlements are needed.

6. According to the probabilistic patents theory, the owner of a patent only has a probabilistic right, and is not entitled to conclude an agreement that would harm consumers. It is not easy, however, to identify the agreements that might have such effects. The legal standard proposed by Shapiro compares the welfare for consumers in the case of patent settlements with the one that would be achieved with patent litigation. As he puts it, "*a settlement must leave consumers as well off as they would have been from ongoing patent litigation*."[11] If consumer welfare is lower in the case of patent settlements than in the case of patent litigation, the agreement should be considered anticompetitive, and prohibited. In this context, the existence of large reverse payments in excess of the expected costs of litigation leads to the presumption that the patent is weak and that the settlement should be considered anticompetitive.[12]

7. In addition, if we accept Shapiro's normative standard, the concept of potential competitor under article 101 TFEU should also be redefined. Traditionally, patents were presumed valid until considered void by the competent authorities; generic producers could not, therefore, be considered potential competitors, as patents were well-defined rights and the entry of competitors could only occur in violation of the patents. Through the lens of the probabilistic patent rights theory, potential competitor must be redefined and should also be considered probabilistic: "(…) *a generic entrant would still be seen as a potential competitor if there is a sufficiently high probability that it would actually prevail in litigation and therefore be able to enter the market*."[13]

8. The probabilistic patent rights theory was also considered by the Supreme Court in the USA. The US pharmaceutical sector is regulated by the Hatch-Waxman Act.[14] The purpose of this Act is encouraging generic manufacturers to challenge invalid patents from the originator firm by offering a 180-day market exclusivity for the first producer challenging the patent to enter the market and to offer generic drugs at a cheaper price. Although in the EU there is no equivalent to the Hatch-Waxman Act, pay-for-delay agreements have also been used frequently in Europe to buy the originator company time to establish a new version of its drug. Such use of pay-for-delay contracts clearly raises antitrust concerns.[15]

9 S. Gallasch, Activating *Actavis* in Europe – the Proposal of a "Structured Effects-Based" Analysis for Pay-for-Delay Settlements, *University of East Anglia Centre for Competition Policy Working Paper* 15-3, 2016.

10 M. A. Lemley and C. Shapiro, Probabilistic Patents, 19(2), *Journal of Economic Perspectives*, 2005, pp. 80, 94–95. *See also* D. Encaoua and Y. Lefouili, Licensing Weak Patents, 57 *Journal of Industrial Economics*, 2009, pp. 492–525.

11 C. Shapiro, Antitrust Limits to Patent Settlements, (2003) 87 *RAND Journal of Economics*, 391.

12 Ibid., pp. 397–408. Shapiro's theory has, however, been criticised, because it cannot be applied to all types of agreements. *See* P. Régibeau, "Pay-for-Delay": What Do We Disagree On? 9(2) *Competition Policy International*, 2013, p. 122.

13 Ibid., p. 122.

14 Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98/417.

15 European Commission, Pharmaceutical Sector Inquiry: Final Report (2009), § 1010.

III. The *Lundbeck* case: Background

9. On 8 September 2016, the General Court (GC) ruled in *Lundbeck* that competition law rules—namely, Article 101 TFEU—apply to patent settlement agreements with reverse payment, and that these should be considered restrictions of competition by object.[16] Lundbeck is a Danish pharmaceutical company which manufactures citalopram, a blockbuster antidepressant. The protection afforded by the firm's compound patent had expired by 2002 in most countries, but over time the company developed other more effective processes for the production of citalopram. Nevertheless, several generic producers were preparing their entry into the market. Lundbeck claimed an infringement of its intellectual property (IP) rights and concluded six agreements concerning citalopram with four generic manufacturers active in the production and/or sale of generic medicinal products. In those agreements, the generic producers committed not to enter the market, and Lundbeck offered substantial payments in return.

10. The GC upheld the European Commission's approach to pay-for-delay agreements. In fact, in the cases *Fentanyl* and *Servier* the Commission had also applied EU competition law provisions to those agreements.[17] In *Lundbeck*, it found that the originator firm and the generic producers were at least potential competitors in the European Economic Area (EEA). Moreover, the agreement involved making significant payments to the generic producers, which were approximately equivalent to the profits expected with the successful entry of the generics into the market. It also restricted market entry for generic producers. As a result, the agreement infringed Article 101 TFEU, and the Commission imposed fines on all the firms involved. The decision was upheld by the GC in September 2016 and, on 18 November 2016, Lundbeck filed an appeal before the Court of Justice against the judgment of the GC.[18]

11. It should be noted, however, that the principle laid down by the GC in the *Lundbeck* case is that reverse payments are not always problematic. This is particularly the case when that payment is linked to the strength of the patent and does not intend to delay the market entry of generics.[19] That was also the stand taken by the Commission in the Annual Pharmaceutical Sector Inquiry, which referred agreements with limitation on generic entry with value transfer as the only ones raising antitrust concerns. Other types of settlements, such as agreements with no limitation on generic entry—so that the generic firm can enter the market freely—or agreements with limitation on generics entry without value transfer from the originator firm—for instance, allowing the generic firm to distribute the drugs of the originator—were not problematic.[20]

12. Therefore, both the Commission and the GC focused principally on the size of the payments, seemingly leaning on the lessons of the probabilistic patent rights theory. Large reverse payments, unexpectedly high litigation costs and the generic firms' expected market profit, were considered proof that the parties believed the patent was likely to be invalid or at least not infringed by the generic manufacturers, and the main goal of the agreement was the exclusion of potential competitors.[21] In other words, when the reverse payment amount exceeds the originator's anticipated litigation costs, it will not only delay the expected market entry of the generic firm, but will also exceed "*the probabilistic patent scope according to the patent holder's own probability estimate*."[22] This test would have the advantage of not requiring an assessment of the patent's merits, which is extremely hard for antitrust authorities, while providing an easy and practical criterion of legality.

13. Taking this test into account, and considering that Lundbeck's agreements were similar to market-sharing deals,[23] the GC applied Article 101(1) TFEU. The Court concluded that those agreements were restrictive of competition by object.[24] Since the originator firm blocked all competition during a specified period, the arrangements allocated time instead of a territory (as in traditional market-sharing).[25] The examination of the hypothetical counterfactual scenario was considered irrelevant *in casu*, as the CG did not find it necessary to analyse the effects of the agreements on the market under Article 101(1), and the legal exception of Article 101(3) TFEU was found to be inapplicable.[26]

16 *H. Lundbeck A/S and Lundbeck Ltd v. European Commission*, Case T-472/13, 8 September 2016.

17 Case AT.39685 — *Fentanyl*, and case AT.39612 — *Perindopril (Servier)*.

18 Case C-591/16 P, Appeal brought by H. Lundbeck A/S, Lundbeck Ltd against the judgment of the General Court (Ninth Chamber).

19 *Lundbeck* judgment, § 350.

20 European Commission, 6th Report on the Monitoring of Patent Settlements (period: January–December 2014), 2 December 2015.

21 C. Shapiro, Antitrust Analysis of Patent Settlements Between Rivals, *Antitrust Magazine*, 2003, pp. 70–77, at p. 72.

22 E. Elhauge and A. Krueger, Solving the Patent Settlement Puzzle, 91 *Texas Law Review*, 2012, p. 282.

23 The uncertainty of patent litigation was replaced by the certainty of delaying generic entry against a large payment.

24 *Lundbeck* judgment, §§ 161, 355. For a critical view of this solution, *see* R. Subiotto QC and J. Figus Diaz, Lundbeck v Commission: Reverse Payment Patent Settlements as Restrictions of Competition by Object, 8(1) *Journal of European Competition Law & Practice*, 2017, p. 27.

25 *See FTC v. Watson Pharmaceuticals, Inc. et al.*, Supreme Court, No. 12-416, On Writ of Certiorari to the US Court of Appeals for the Eleventh Circuit, Brief Amicus Curiae. January 29, 2013. *See*, however, K. D. McDonald noting that the mere "*existence of the patent right destroys any analogy with market division*."K. D. McDonald, Because I Said So: On the Competitive Rationale of *FTC v. Actavis*, 28(1) *Antitrust*, 2013, p. 37.

26 *Lundbeck* judgment, §§ 473, 720.

IV. The concept of "potential competitor" in the *Lundbeck* case

14. Ruling that pay-for-delay agreements are restrictions of competition by object was only possible because the GC considered generic producers and Lundbeck to be potential competitors. According to the court, the generic firms had real concrete possibilities and capacity to enter the market and to compete with established undertakings.[27] Their entry was an economically viable strategy, supported by factual evidence. In fact, the generic producers had taken steps, before the expiry date of the patent, to develop viable production processes and obtain marketing authorisations, and they had already concluded contracts for the supply of generic products.[28] As confirmed by the GC, potential competition takes place in two phases in the pharmaceutical sector. The first phase may start several years before patent expiry on an active pharmaceutical ingredient (API), when generic firms start developing viable production processes. In the second phase, generic firms prepare for actual market entry by making applications for marketing authorisations (MAs) and establishing distribution networks. Lundbeck's process patents were not, therefore, capable of blocking all possibilities of market entry open to the generic firms.

15. As the GC mentioned in that case, according to the undertakings involved the crystallisation patent on which Lundbeck relied in order to close the market entry in the United Kingdom had a good chance (around 60%) of being held invalid by a court.[29] In addition, generic producers did not consider the product as novel. Generic undertakings could thus "*enter the market ' at risk*,"[30] and this type of conduct, which has been criticised for endorsing potentially unlawful conduct,[31] should not be considered an infringement of patent law according to the GC.

V. The *Lundbeck* approach in the light of the previous praxis on exclusive rights: What is new?

16. The solution held by the GC in the *Lundbeck* case has been criticised for being seemingly at odds with the approaches followed by the Commission and the EU courts in their previous decisions.[32] The Commission had already decided that generic firms could not enter the market in a sustainable way if patent litigation was ongoing.[33] The GC, on its part, had already decided in cases involving exclusive rights that potential competition could be set aside. This appears to be the case, for instance, in *E.ON Ruhrgas*,[34] which dealt with market-sharing agreements between energy distribution companies by which the undertakings involved agreed not to supply electricity or gas in each other's territories. Here, the GC appeared to suggest that firms could not be considered potential competitors if there were territorial monopolies granted by the State. In *Lundbeck*, however, the GC pointed out that the *E.ON Ruhrgas* case should be seen as a totally different matter. In the latter case the national legislation created a de facto monopoly, and undertakings were not treated as potential competitors because market entry was not an economically viable strategy. Nonetheless, in *Lundbeck* the legal monopoly granted to the patent holder was not considered sufficient to block the potential entrance of generic firms into the market.[35]

17. Following this logic, it would seem that not all exclusive rights can be considered equal as regards potential competition. While some exclusive rights granted by the State exclude potential competition, the validity of others—such as patents—is uncertain. If the outcome of patent litigation is unclear, the patent holder does not have the right to exclude rivals who are allegedly infringing competition (the alternative could be to seek a preliminary injunction).[36] To put it differently, although there is a presumption of patent validity, there is no certainty as to the result of the patent litigation. Any decision on that issue would consequently be purely speculative. On the other hand, it has been suggested that potential competition could not exist where market entry depends on the infringement of an intellectual property right. For example, in the *Teva/Cephalon* case, as the

27 Ibid., § 128.

28 Ibid., §§ 100, 104, 131.

29 Ibid., §§ 122, 254.

30 Ibid., §§ 96, 281.

31 S. Lawrence, E. Bond, and M. Hunt, Survey – Genentech, Lundbeck, Paramount and Others: A Survey of Cases at the Intersection Between Competition Law and IP Law in the Past Year, 8(1) *Journal of European Competition Law & Practice*, 2017, p. 66.

32 Ibid., p. 70.

33 *See* Case No. COMP/M.6258 – *Teva/Cephalon*.

34 Case T-360/09 *E.ON Ruhrgas and E.ON v. Commission* ECLI:EU:T:2012:332, § 84.

35 Ibid., §§ 100 and 816.

36 Lemley & Shapiro (2005) above, p. 94.

patent litigation was ongoing, the Commission assumed that the generic firms could not have entered the market in a sustainable way.[37] A similar approach was followed by the Commission in the Guidelines on the application of Article 101 TFEU to technology transfer agreements, which confirmed that the possibility that existing IP rights act as a barrier to entry should be considered. The licensee is not a potential competitor if it cannot enter the market without infringing the IP rights of the other party.[38]

18. The GC ignored all these arguments and clarified that Lundbeck's patents were not considered to constitute a barrier to entry. Therefore, potential competition may exist before the expiry of a patent, as the Court of Justice had already established in the *AstraZeneca* judgment.[39] Although the solution presented has been criticised for rendering the presumption of validity afforded to patents by statute meaningless,[40] the strength or weakness of the patent is still relevant. In fact, the weakness of the patent is evidenced when the originator firm is paying the generic firm large amounts of cash to avoid the risk of litigation. Large reverse payments are thus inconsistent with a claim by the patent holder that its patent would probably be found valid if litigated, and should be presumed to be anticompetitive.

19. Finally, it should be mentioned that the *Lundbeck* analysis set aside the approach taken in the *Windsurfing* case,[41] which accepted the scope of the patent test. This test is somewhat problematic from the point of view of competition law, as it leads to the presumption that the generic product infringes the patent when the issue was not decided. Moreover, it suggests that patents are immune to antitrust laws. Yet the case law of the Court of Justice followed a quite different approach and never exempted patent settlements from antitrust scrutiny.[42] The scope of a patent is not, it appears, immune to antitrust laws; on the contrary, antitrust laws and patent laws should work together to define that scope. Setting aside the scope of the patent test, and allowing competition law to intervene along with patent law in the definition of the scope of the patent, would seem like the best solution.

20. The approach followed by the GC in the *Lundbeck* case is therefore coherent with the dominant economic literature and particularly with the theory of probabilistic patent rights. In fact, the GC acknowledged the uncertainties inherent to the patent system, as patents are issued with little examination and they will probably be invalid. It held that "*the presumption of validity cannot be equated with a presumption of illegality of generic products validly placed on the market which the patent holder deems to be infringing the patent*" and that "' *at risk' entry is not unlawful in itself.*'"[43] Moreover, the GC has relied in the previous case law of the Court of Justice and confirmed that, given the economic and legal context, "*there are real concrete possibilities for the undertakings concerned to compete among themselves or for a new competitor to enter the relevant market*."[44] Furthermore, the GC decided that there is a high probability that generic firms would prevail in litigation: the parties "*estimated the probability that its crystallisation patent would be held invalid at 50 to 60 per cent*."[45] In addition, the GC appears to have accepted that the "*size of a reverse payment may constitute an indicator of the strength or weakness of a patent, as perceived by the parties to the agreements*,"[46] and that the higher the originator firm estimates the chances of its patent being found invalid, "*the more money it will be willing to pay the generic undertakings to avoid that risk*."[47]

21. In conclusion, the court held that it was the "*disproportionate nature of such payments*," combined with several other factors, that led to the finding that the agreements at issue had as their object the restriction of competition.[48] Moreover, the transfer of value "*replaces the autonomous assessment, by the parties, of the strength of the originator undertaking's patents and the assessment of their chances of succeeding in potential litigation based on those patents or concerning their validity*."[49] This means that the GC, without entering into an assessment of the validity of the patent, applied a test which is easy to perform,[50] benefiting from the theoretical framework developed in the context of probabilistic patent rights.[51]

22. To fully understand the *Lundbeck* judgment, a brief reference to the approach taken in the United States is necessary. Since a detailed analysis is provided elsewhere in this on-topic paper,[52] the focus here will be simply on some developments that are of particular relevance to this discussion. After a long period of inconsistent case law and conflicting views between the FTC and some courts, the Supreme Court held in *Federal Trade Commission v. Actavis* that large payments made to a generic firm to prevent it from entering the market infringed antitrust rules, subject to a rule of reason analysis. This is so even

37 *Teva/Cephalon*, § 98.

38 Communication from the Commission, Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements, (2014) C89/03, §§ 129-132.

39 T-321/05 *AstraZeneca v. Commission*, ECLI: EU:T:2010:266, §§ 121, 163.

40 K. D. McDonald (2013) above, p. 74.

41 C-193/83 *Windsurfing International v. Commission*, 193/83, ECLI: EU:C:1986:75, § 26.

42 C-65/86 *Bayer and Maschinenfabrik Hennecke*, ECLI: EU:C:1988:448.

43 *Lundbeck* judgment, §§ 121 and 122.

44 Ibid., § 123.

45 Ibid., § 122.

46 Ibid., § 353.

47 Ibid.

48 Ibid., § 354.

49 Ibid., §§ 354 and 360.

50 On the perception of the probabilistic patents by the GC, *see* I. Lianos and V. Korah with P. Siciliani, *Competition Law: Analysis, Cases and Materials* (Hart, 2017), Chapter 13.

51 It should also be noted that the GC follows the principle that competition law only protects lawful competition, and is not intended to protect firms that might infringe IP rights when entering into the market. As Judge Posner put it, "[w]*e do not want an efficient market in stolen goods*." Cf. R. A. Posner, *Economic Analysis of Law*, 5th ed. 1998, 91.

52 K. Fournier, The Notion of "Potential Competitor" in US Antitrust Enforcement: Pragmatism and Legal Certainty, *Concurrences* No. 2-2017.

if the patent settlement is within the scope of the patent, excluding only products allegedly infringing a presumptively valid patent. According to the Supreme Court, the presence of a significant reverse payment in a patent settlement agreement can provide a "*workable surrogate for the weakness of a patent, without a court having to carry out a detailed analysis of the validity of that patent*."[53] The Supreme Court thus rejected both the scope of the patent test and the quick look test.[54] It left, however, several questions unanswered. For instance, it did not clarify whether reverse payments should also include value transfer, such as distribution or licence agreements, and it did not detail when a payment is large and unjustified, or how to assess the benefits of the settlement.

23. Some of these issues were addressed by the Third Circuit Court in the *King Drug* decision in June 2015, and the First Circuit Court in the *Loestrin* decision of February 2016. Those judgments confirmed that the principle laid down in *Actavis* can be applied to payments in forms other than cash. The Supreme Court was asked to review and reverse the Third Circuit's unanimous panel decision in *King Drug*, which considered that a no-authorised generic deal (that is to say, the originator firm agrees not to launch its own authorised-generic alternative when the first generic company begins to compete) can be considered a transfer of value to the generic firm and can be scrutinised under antitrust law.[55]

24. Notwithstanding the questions left unanswered, the approach followed in *Actavis* also takes into account the probabilistic patent rights theory, and the results achieved are not very different from those obtained in the EU context. In fact, in spite of the different regulatory context, the solution proposed by the GC in *Lundbeck* is consistent with the one followed by the Supreme Court: both considered that patent settlements with a high level of value transfer should be subject to antitrust scrutiny, setting aside the scope of the patent test, and both insisted on the uncertainties of this type of IP rights and the specificities of the pharmaceutical sector, calling into the equation the probabilistic patent rights theory.

VI. Conclusion

25. The specific solution followed in the *Lundbeck* case for pay-for-delay agreements in the pharmaceutical sector must be considered through the lens of probabilistic patents. The GC appears to propose a new approach regarding to the concept of potential competitors. It applied Article 101 TFEU to pay-for-delay agreements and explained that the legal monopoly granted to the patent holder will not exclude potential competition if generic firms have the ability and capacity, in a short period of time, to enter the market. In fact, potential competition may exist even before the exerted patent has expired. Additionally, apparently inspired by the probabilistic patent rights theory, the GC moved away from the traditional view of potential competitor, and decided that generic firms could be potential competitors, if there was a high probability that they would prevail in litigation. Finally, the GC accepted that the existence of large reverse payments should be seen as an indicator of the weakness of the patent and of the anticompetitive nature of patent settlements. ■

53 Judgment of the Supreme Court of the United States of 17 June 2013, *Federal Trade Commission v. Actavis*, 570 U.S. (2013).

54 *Federal Trade Commission v. Actavis Inc. et al*. Certiorari to the United States Court of Appeals for the Eleventh Circuit, p. 122. *See also Schering-Plough Corp. v. FTC*, 402 F.3d 1065, 1076 (11th Cir. 2005), which proposed a test of presumptive illegality followed by a "quick-look" analysis.

55 *King Drug Company of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. June 26, 2015). and *Rochester Drug Co-Operative, Inc. v. Warner Chilcott Co.* (*In re Loestrin* 24 FE Antirust Litig.), 2016 U.S. App. LEXIS 3049 (1st Cir. February 22, 2016).

Lundbeck and the economics of potential competition

Derek Ritzmann
driztmann@compasslexecon.com
Senior Vice President, Compass Lexecon, Hong Kong

I. Introduction

1. The recent decision in the *Lundbeck*[1] case before the General Court depended critically on the scope of the concepts of "potential competition" and "potential competitor." This paper considers the insights that economics can bring to the question of how we might think about how to define and delineate these concepts, including by reference to contestable markets ideas, which are the focus of a section of this paper and are explained in some detail below. It also makes some suggestions regarding possible future developments in these concepts in the courts, and how competition practitioners might go about sharpening the way these concepts are presented and argued.

II. The *Lundbeck* case and the concept of potential competitor

2. The case law and precise circumstances of the *Lundbeck* case have been recounted in detail elsewhere: in the Commission decision on this case; in the judgment of the General Court; and in other papers in this On-Topic edition[2]. I will therefore not recount these circumstances in significant detail afresh here. It is worthwhile, however, to note several key aspects of the case.

3. Lundbeck, a Danish pharmaceutical company, held patents in the active pharmaceutical ingredient and two original production processes concerning the antidepressant drug citalopram. As these patents approached expiry, Lundbeck concluded a series of settlement agreements ("the agreements") with four generic manufacturers, under which Lundbeck made substantial payments to each of the generic companies, and in consequence of which the generic companies agreed not to enter the citalopram market for a defined period. Agreements of this kind had previously attracted the attention of the United States antitrust agencies in the "pay-for-delay" cases. With its Pharmaceutical Sector Inquiry of 2009 forming the backdrop and providing some guiding principles,[3] the European Commission in 2013 found the agreements to have contravened Article 101 TFEU as a restriction of competition by object.[4] Lundbeck appealed the Commission's decision, and in 2016 the General Court upheld the Commission decision.[5]

4. A core question was whether an agreement with a producer who is not in the market, but who might be in the market as a "potential competitor," could be considered to be an anticompetitive agreement for the purposes of 101 TFEU. As a threshold issue, Article 101 is not triggered unless the parties to the agreements are actual or potential competitors. A fundamental question for the court therefore was whether the generic producers, who had not yet entered the market, were potential competitors for the purposes of Article 101. If these generic producers were found to be potential competitors in the relevant economic and legal context, this would lead to the conclusion that the agreements were restrictive of competition by object in that they constituted cartel-like arrangements without a reasonable objective purpose other than the restriction of competition.

5. The Court drew on existing case law to outline the key jurisprudential principles regarding the existence of potential competition and competitors.[6] The analysis of competition in a market must include existing competition and also potential competition to determine whether "*there are real concrete possibilities for the undertakings concerned to compete among themselves or for a new*

1 Case T-472/13 *H. Lundbeck A/S and Lundbeck Ltd v. European Commission* ("*Lundbeck*").

2 See e.g. N. Dunne, Why Protect Potential Competition? *Concurrences* No. 2-1017, in the same On-Topic as this paper.

3 Pharmaceutical Sector Inquiry Report

4 COMP/AT.39226 — *Lundbeck*.

5 *Lundbeck*.

6 Case T-360/09 *E.ON Ruhrgas and E.ON v. Commission*; Cases T-374/94, T-375/94, T-384/94 and T-388/94 *European Night Services and Others v. Commission*; Case T-461/07 *Visa Europe and Visa International Service v. Commission*.

competitor to enter the relevant market and compete with established undertakings" in light of the structure of the market and its economic and legal context. [7] This means that, in order to determine whether an enterprise is a potential competitor, the Commission must determine if, in the absence of the agreement, "*there would have been real concrete possibilities*" for the enterprise to enter the market and to compete with the existing market participants.[8] In other words, the agreement must be assessed against the counterfactual—what would have happened in the absence of the agreement? Highly relevant therefore is whether the supposed potential competitor had the ability and incentive to enter the market, the agreement notwithstanding.[9]

III. The economics of potential competition and potential competitors

6. So what is potential competition, and who is a potential competitor? The Court's judgment and the surrounding case law provide helpful guidance in this respect. However, the discipline of economics in competition enforcement has long considered the question of potential competition for a variety of purposes, including for mergers clearances among other reasons. This section outlines some relevant aspects of the economics of potential competition.

7. It is widely accepted that competition law is to a significant extent an economic law, and that many of the substantive jurisprudential concepts in modern competition law are arguably need to be understood through a lens of economic reasoning.[10] Economic reasoning underpins areas of competition law ranging from modern merger analysis, the analysis of vertical agreements, abuse of dominance/monopolization, and the legal presumption that cartels inherently cause harm to competition. In this sense, John Maynard Keynes's famous observation that "[p]*ractical men who believe themselves to be quite exempt from any intellectual influence, are usually the slaves of some defunct economist*,"[11] may in the context of modern competition law, well have been expressed as "competition practitioners who believe themselves to be quite exempt from any economic influence, are usually the slaves of some defunct economist." From this perspective, it is valuable to consider how the body of economics views the concepts of potential competition, and therefore what constitutes a potential competitor.

8. Economics has understood the importance of potential competition as a mechanism that influences the behaviour of a market since at least the 1950s. Barriers to entry were arguably the first of many ways in which potential competition entered competition analysis by way of the economic literature. Joe Bain, a founder of the structure-conduct-performance (SCP) school of thought in industrial organization, first proposed and tested barriers to entry as a central determinant of industry performance.[12] The concept that low barriers to entry facilitate competitive entry in response to high profits, and thereby discipline market incumbents, first comes to us from Bain's and other contemporary works. Bain's core conclusion that entry barriers are a critical factor in determining the competitive outcomes in an industry has long been familiar to competition practitioners everywhere. The discipline of potential competition is implicitly (or explicitly) recognized every time a merger clearance filing discusses barriers to entry and potential entrants into a market as a determinant of the post-merger level of competition.

9. Further important developments in game theory, in particular in dynamic games, built on these foundations to provide ever more sophisticated structures for understanding how existing competitors react to the threat of new competition, and how potential new competition may discipline existing market participants.[13] In particular, our understanding of the different categories of entry barriers has become enriched in practical competition law and economics in step with the progressive enrichment of the literature in this field. In particular, we now have a sophisticated understanding of the ways in which different mechanisms such as switching costs, lock-in effects and network externalities can influence consumers by being a source of "stickiness" to existing suppliers that makes entry for a potential market contestant more difficult, and thereby can weaken the discipline that entry potentially exercises on the market.

7 *Lundbeck*, § 99.

8 *Lundbeck*, § 100.

9 *Lundbeck*, § 101.

10 The following may be of interest to the reader with regard to this broader development which goes beyond the scope of this paper: A. Gavil, W. Kovacic, J. Baker, and J. Wright, *Cases, Concepts and Problems in Competition Policy*, 3rd ed. (West Academic Publishing, 2017); P. Areeda, L. Kaplow, and A. Edlin, *Antitrust Analysis: Problems, Texts, and Cases*, 7th ed. (Aspen Publishers, 2013); J. Kwoka and L. White, *The Antitrust Revolution*, 6th ed. (Oxford University Press, 2013); R. Posner, *Antitrust Law: An Economic Perspective* (University of Chicago Press, 1976); E. Elhauge and D. Gerardin, *Global Competition Law and Economics*, 2nd ed. (Hart Publishing, 2011); L. Kaplow, Antitrust, Law & Economics, and the Courts, 50 *Law and Contemporary Problems*, 1987, pp. 181–216.

11 J. M. Keynes, *General Theory of Employment, Interest and Money* (London: MacMillan, 1936).

12 J. Bain, Economies of Scale, Concentration and the Condition of Entry in Twenty Manufacturing Industries, *American Economic Review*, 44(1), 1954, pp. 15–39; J. Bain, Conditions of Entry and the Emergence of Monopoly, in E. H. Chamberlin (ed.), *Monopoly and Competition and Their Regulation* (Macmillan, 1954), pp. 215–41; J. Bain, Chamberlin's Impact on Microeconomic Theory, in R. Kuenne (ed.), *Monopolistic Competition Theory* (John Wiley, 1967).

13 *See*, for instance, J. Tirole, *The Theory of Industrial Organization* (MIT Press, 1988); M. Motta, *Competition Policy: Theory and Practice* (Cambridge University Press, 2004); and P. Belleflamme and M. Peitz *Industrial Organization: Markets and Strategies*, 2nd ed. (Cambridge University Press, 2015).

10. An important step in our modern understanding of potential competition, and a useful further stepping stone in understanding the importance of entry barriers, is the concept of contestable markets first developed in 1982.[14] This concept has been influential in expanding our understanding of the possible role of potential competition in influencing the behaviour of existing participants in a market. Furthermore, the critique and limits of this concept have helped us to focus on the conditions in which potential competitors will discipline a market and the conditions in which they will not. These conditions in turn have important implications for who may be a potential competitor for the purposes of *Lundbeck* and similar cases.

11. The contestable markets hypothesis states that a market outcome is sustainable when no new firm (using existing technology) can profitably enter the market by offering lower prices than the incumbents and serving some or all of the existing demand at the new, lower prices. A perfectly contestable market is a market which is only in market equilibrium when the market outcome is sustainable. In consequence, the equilibrium market outcome in a perfectly contestable market is that total costs will equal total revenues, that is, total market profits will be zero. If prices are such that revenues exceed costs, a new firm could profitably enter at lower prices, meaning that the prices are not sustainable but will instead be driven down and confined to a sustainable level, which is where revenues equal costs. In a market served by a monopoly (for instance a natural monopoly), this results in prices being equal to average costs—the outcome in essence sought by many natural monopoly regulatory regimes. In a contestable market served by several firms, prices will be constrained by free entry to being equal to marginal costs, since any deviation in price will create opportunities for firms profitably to adjust their prices and outputs and thus will not be stable. This market outcome therefore mimics the outcome achieved in perfectly competitive markets.

12. This is a striking result. In a world characterized by perfectly contestable markets, potential competition disciplines all such markets to achieve the socially desirable outcome, including in natural monopoly markets. In such a world, competition authorities would have little to do, because potential competition is all-disciplining—and potential competitors would be a very wide category indeed.

13. However, the conditions under which markets are perfectly contestable are strong. This places important limits on the application of contestable markets concepts and conclusions, which in turn suggests important limits on who should be considered a potential competitor. The strongest form of a perfectly contestable market occurs where entry and exit can happen freely and immediately. Under those conditions, no firm (including a monopoly) can raise prices above the competitive level because immediate and free entry would immediately defeat the price rise.[15] However, most industries have some, even if modest, barriers to entry. In the generally realistic situation where there are barriers to entry, it is important how quickly the incumbents' prices can move, in particular in response to entry. Where existing market participants' prices are restrained to responding more slowly than entry can take place, the perfectly contestable market outcome can be reproduced, because incumbent firms will have similar incentives not to raise prices in a way that would trigger entry.[16] However, where prices can respond more quickly than entry can take place, incumbents can maintain profitable prices without similar discipline from the fear of immediate entry, as they can reduce prices sufficiently quickly as soon as they see entry taking place and in advance of the entry being completed.[17]

14. These restrictions on the applicability of contestable markets concepts have important consequences for the analysis of potential competition. Potential competition from potential entrants has a strong restraining effect on existing players' market behaviour when entry is free and immediate, or when there are modest barriers to entry and entry can take place more quickly than incumbents can adjust their prices. In the absence of these conditions, the potential competition from entrants is weakened. Of particular importance is the existence of sunk costs. The absence of entry barriers includes, in the well-known way, the absence of sunk costs (costs that are not recoverable) by entrants. Where there are sunk costs (or other entry barriers), and where incumbents' prices can adjust sufficiently freely, the contestable markets hypothesis breaks down, and the market discipline exerted by potential entrants is correspondingly weakened. This in turn arguably has important consequences for the analysis of potential competition and potential competitors; I now turn to this discussion.

IV. Implications for the jurisprudence and concluding words

15. The Court in *Lundbeck* has provided helpful guidance regarding the legal threshold of what constitutes "potential competition" and therefore a "potential competitor." A potential competitor is a potential market participant who has "real concrete possibilities" of entering the market. However, this definition, when taken

14 W. Baumol, J. Panzar and R. Willig, *Contestable Markets and the Theory of Industrial Structure* (New York: Harcourt Brace Jovanovich, 1982).

15 W. Baumol and R. Willig, On the Theory of Perfectly-Contestable Markets, in J. E. Stiglitz and F. Mathewson (eds.), *New Developments in the Analysis of Market Structure* (Cambridge, Massachusetts: The MIT Press, 1986), pp. 339–65.

16 Ibid.

17 J. Farrell, How Effective is Potential Competition?, *Economics Letters*, 20, 1986, pp. 67–70; R. J. Gilbert and R. G. Harris, Competition with Lumpy Investment, *RAND Journal of Economics*, 15, 1984, pp. 197–212; and R. J. Gilbert, Preemptive Competition, In J. E. Stiglitz and F. Mathewson (eds.), *New Developments in the Analysis of Market Structure* (Cambridge: MIT Press, 1986), 90–125.

on its own, and no matter how helpful it is, risks being rather amorphous. As with many other areas of competition law, economics can provide sharper guiding lines regarding what potential entrant into a market should, or should not be considered a "potential competitor."

16. The economic literature outlined above has potentially important implications for the potential competitor analysis. A potential market entrant in the presence of barriers to entry and where prices can move more rapidly than entry takes place will not exert similar market discipline on incumbents as in a situation where entry is free and immediate. These notions are deeply entrenched in modern mergers analysis, in particular in respect to the relevance of entry. The United States Horizontal Merger Guidelines state that "[a] *merger is not likely to enhance market power if entry into the market is so easy that the merged firm and its remaining rivals in the market, either unilaterally or collectively, could not profitably raise price or otherwise reduce competition compared to the level that would prevail in the absence of the merger. Entry is that easy if entry would be timely, likely, and sufficient in its magnitude, character, and scope to deter or counteract the competitive effects of concern*."[18]

17. This demonstrates the importance of the likelihood and the timeliness of entry in constraining market behaviour in the context of mergers analysis, and is consistent with the economic literature. Very similarly, the EU Horizontal Merger Guidelines provide that "*for entry to be considered a sufficient competitive constraint on the merging parties, it must be shown to be likely, timely and sufficient to deter or defeat any potential anti-competitive effects of the merger*,"[19] and go on to provide a great wealth of helpful and nuanced detail around these core criteria.

18. Consider the analysis of a merger where there is a potential entrant in the presence of high barriers to entry. Such a potential entrant may be judged to be unlikely to exert appreciable competitive discipline on a market because it would find it difficult to enter the market—these are the lessons from bodies of economics including those I have outlined above. In such a case, a merger would be unlikely to be cleared merely because of the existence of such an unlikely potential entrant. The likelihood of that potential entrant exerting sufficient potential competition, and therefore of being an appreciable potential competitor, would probably be judged to be too remote.

19. Then consider the same potential entrant, in an analogous market in the presence of the same high entry barriers, but in the context of a *Lundbeck*-style case. Would that potential entrant be considered to be a potential competitor in a *Lundbeck*-style case? Under the court's analysis in *Lundbeck*, it would seem that it would: it would seem that this potential entrant might well be considered a "potential competitor" if a mere "real concrete possibility" of entry exists, notwithstanding the high barriers to entry. However, in a merger case involving the same market and the same potential entrant, the entrant might well be discounted as imposing the discipline of potential competition if the entry is "concretely possible" but not "likely," and would therefore not be considered a likely "potential competitor" in this analogous situation.

20. One can see from this juxtaposition of scenarios that there exists the possibility for analytical and doctrinal inconsistency arising from analogous fact scenarios, in the context of searching for the same concept of potential competition and potential competitor, but when applied to different competition law provisions. In future decisions involving potential competition and competitors, the courts may wish to consider emphasizing doctrinal consistency across these concepts, including considering how these comparable concepts are applied in the well-established mergers jurisprudence and practice.

21. On the other side of the equation, parties and their legal representatives facing *Lundbeck*-style issues may wish to draw on economic analysis of potential competition to ground their positions on solid foundations. Competition authorities and courts increasingly look to rigorous economic analysis in merger clearance, abuse of dominance, vertical restrictions, and other cases involving economic effects. Potential competition is a concept as solidly grounded in economic analysis as those other areas of competition, meaning that the analysis of whether a party is a potential competitor is equally amenable to economic thought and argument. The General Court has spoken, but this need not be the final word. It is entirely feasible that future courts will seek a jurisprudence of potential competition that displays greater doctrinal consistency and convergence with other areas of competition law: a consistency that may converge around the economic concepts. ■

18 US Department of Justice and the Federal Trade Commission (2010), Horizontal Merger Guidelines, Washington, D.C., p. 28.

19 European Commission, Guidelines on the Assessment of Horizontal Mergers under the Council Regulation on the Control of Concentrations between Undertakings (2004) C31/03.

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